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The Evaluation of Methods for the Prospective Patient Safety Hazard Analysis of Ward-Based Oxygen Therapy

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ABSTRACT

When even seemingly benign and routine processes fail in healthcare, people sometimes die. The profound effect on the patient's families and the healthcare staff involved is clear (Vincent and Coulter, 2002), while further consequences are felt by the institution involved, both financially and by damage to reputation. The trend in healthcare for learning through experience of adverse events is no longer a viable philosophy (Department of Health,Sir Ian Carruthers OBE and Pauline Philip, 2006).

In order to make progress towards preventative learning, three Prospective Hazard Analysis (PHA) methods used in other industries were evaluated for use in the area of ward based healthcare. Failure Modes and Effects Analysis (FMEA), Fault Tree Analysis (FTA) and Hazard and Operability Analysis (HAZOP) were compared to each other in terms of ease of use, information they provide and the manner in which it is presented. Their results were also compared to baseline data produced through empirical research.

Oxygen Therapy was used in this research as an example of a common ward based therapy. The resulting analysis listed 186 hazards almost all of which could lead to death, especially if combined.

FTA and FMEA provided better system coverage than HAZOP and identified more hazards than were contained in the initial hazard identification method common to both techniques. FMEA and HAZOP needed some modification before use, with HAZOP requiring the most extensive adjustment. FTA has a very useful graphical presentation and was the only method capable of displaying causal linkage, but required that hazards be translated into events for analysis.

It was concluded that formal Prospective Hazard Analysis (PHA) was applicable to this area of healthcare and presented added value through a combination of detailed information on possible hazards and accurate risk assessment based on a combination of expert opinion and empirical data. This provides a mechanism for evidence based identification of hazard barriers and safeguards as well as a method for formal communication of results at any stage of an analysis. It may further provide a very valuable vehicle for documented learning through prospective analysis incorporating feedback from previous experience and adverse incidents. The clear definition of systems and processes that form part of these methods provides a valuable opportunity for learning and the enduring capture and dissemination of tacit knowledge that can be continually updated and used for the formulation of strategies for safety and quality improvement.

Keywords:

Healthcare; FMEA; Fault Tree; HAZOP; Hospital; Error; Failure; Clinical Risk; Observation; Questionnaire; Incident Report

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There are so many who have given me much support in the production of this work, that it is sadly impossible to name each one. I will however mention those that I can, and apologise unreservedly to those that I do not.

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PUBLICATIONS

The following publications have resulted from this research.

Durand M, Fuller G, Sizer J; “Applying Industry Standard Techniques for the Risk Assessment of Ward Based Therapies”. *The Risk Casino - Are You Playing To Win?; Royal United Hospital,Bath; 19 April 2006*; The Institute of Physics and Engineering in Medicine.

Durand M, Tetlow S and Sizer J. “Patient Safety with Oxygen Therapy”. *Proceedings of the 12th Annual Scientific Meeting; Cambridge, 6-8 September 2006*; Whish GJ, editor. : The Institute of Physics and Engineering in Medicine; York; 2006.

Durand M, Fuller G, Hurst J, Luettel D, Niblett D, Snape S, Sizer J; “A Systematic Review of Reported Incidents Involving Oxygen Therapy” Submitted for publication.

Further papers based on chapters in this thesis are in the draft stage.

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List of Abbreviations

The following abbreviations, used in the text of this document, are listed here in alphabetical order.

ALARP	As Low As Reasonably Practicable
ASTM	American Society for Testing and Materials
BBC	British Broadcasting Corporation
BMJ	British Medical Journal
CNST	Clinical Negligence Scheme for Trusts
CO_2	Carbon Dioxide
COPD	Chronic Obstructive Pulmonary Disease
EPC	Error Producing Condition
ETA	Event Tree Analysis
FMEA	Failure Modes and Effects Analysis
FMECA	Failure Modes and Effects Criticality Analysis
FTA	Fault Tree Analysis
HAZOP	Hazard and Operability Analysis
HEART	Human Error Assessment and Reduction Technique
HEP	Human Error Probabilities
HFMEA	Healthcare Failure Modes and Effects Analysis
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
Kα	Krippendorff's Alpha
Lpm	Litres per Minute
NAO	National Audit office
NHS	National Health Service

NHSLA	National Health Service Litigation Authority
NICE	National Institute for Clinical Excellence, changed to: National Institute for Health and Clinical Excellence
NPSA	National Patient Safety Agency
O_2	Oxygen
PHA	Prospective Hazard Analysis
PSF	Performance Shaping Factor
PTFE	Polytetraflouroethylene
RLS	Reporting and Learning System
ROP	Retinopathy of Prematurity
RPN	Risk Priority Number
SWIFT	Structured What-If Technique
THERP	Technique for Human Error Rate Prediction
UK	United Kingdom
USB	Universal Serial Bus
VBA	Visual Basic for Applications
VIE	Vacuum Insulated Evaporator
WHO	World Health Organization

Chapter 1 Background and Research Definition

Abstract

This chapter provides an introduction by describing the background to the research and identifying its need and contribution. The relationship with the two hospitals that collaborated in this work is also discussed.

The research question which formed the aims and objective is stated, which leads on to the description of the structure of both the research and the thesis. The methodology is generally described as evaluation, action research aimed at comparing the outcomes from three structured hazard analysis methods to that produced through the use of empirical methods.

1.1 Introduction

If allowed to go unchecked, patient safety hazards can lead to the death of a patient (James Meikle 2002; Hoyle, 2005). Almost every ward based activity, no matter how routine or benign, harbours such risk. Those entering hospital place an enormous amount of trust in the professionals providing their care (Vincent and Coulter, 2002). In some cases, the care they need poses a known risk to them and this is discussed with their clinician in careful consideration. What is almost never discussed however is the risk they face from the 'forgotten' or hidden hazards present in even the most banal processes common on every hospital ward. It is further impossible to discuss those that are as yet unknown. This work was undertaken to place tools for the discovery and illumination of these hazards at the disposal of healthcare professionals.

Little work has been done in evaluating industrial hazard and risk analysis methods for use in healthcare. This may be partly due to the difficulty of evaluating their outcomes in practice, as well as some degree of suspicion by the healthcare 'establishment' regarding the motivation for their use. This research aims to address both these issues by providing an evaluation and a discussion of the contribution of formal hazard analysis to patient safety.

1.1.1 *Aims and Objective*

The following research question was formed from the general consideration of the problem of hazard analysis in healthcare:

> *What is the contribution that formal hazard analysis can make to the assessment of patient safety within ward based therapies?*

Based on this, the hypothesis that a number of hazard analyses based on a common frame of reference, using formal methods, will produce comparable value-added results when tested against empirical research was formed.

This was translated into the following aims:

1. To construct a comprehensive hazard list and risk assessment of a ward based therapy using empirical research.

2. To conduct a small number of structured hazard analyses using different formal methods, each based on a common frame of reference built from empirical research.
3. To evaluate the suitability, advantages and disadvantages of these structured methods to the context of ward based care by comparing the formal hazard analyses to the results from empirical research.

The objective was thus to use evaluation data in the form of a validated, refined hazard list and risk analysis for the assessment of a small number of hazard analysis methods applied to a ward based therapy. This would have the added result of simultaneously producing a comprehensive hazard and risk analysis of the therapy analysed.

1.1.2 *The Background and Collaborations*

The research focused on an evaluation of three 'industrial' methods for prospective hazard analysis, exploring their applicability and contribution to the assessment of patient safety within ward based health care in the United Kingdom.

Oxygen Therapy was used as the subject for the research because senior healthcare professionals at Bedford Hospital were concerned about some obvious, yet unaddressed hazards related to it. They were keen to contribute to the research in the hope that it would help improve the level of care they could provide, especially when oxygen cylinders are in use. Although oxygen therapy is thought to be relatively harmless, in extreme cases, failure can result in the death of a patient.

Having the interest of clinical professionals, especially those in leadership positions, proved to be essential to the research; especially when negotiating access (Mulhall, 2003; Robson, 2002e) and in understanding the clinical/medical issues.

A collaboration was formed between the researcher and the head of the Anaesthetics Department at Bedford Hospital. This was later extended to three further Consultant Anaesthetists in the same department. An honorary contract was extended to the researcher by the Bedford Hospital Research and Development Department.

Conducting research of this nature on only one site is limiting. Having access to two sites opens a wider range of variability, gives access to a larger population and introduces the possibility of comparison between establishments.

A second collaboration was therefore formed with Stoke Mandeville Hospital, part of the Buckinghamshire Hospitals NHS Trust. An honorary contract was also granted to the researcher by the Research and Development department of this hospital.

A further relationship was established with the National Patient Safety Agency (NPSA) for whom it was felt this research may be of use. 5755 anonymised Incident reports were supplied by them for application to this research and an NPSA Research Associate took part in one of the larger studies.

This research was funded by the 'Cranfield Health Partnership' which exists between Cranfield University and a number of local hospitals which includes Bedford Hospital.

1.1.3 *Definition of Scope*

In the context of this research, oxygen therapy was at normal atmospheric pressure; hyperbaric oxygen therapy was excluded as it is not a common ward based procedure.

Both piped and cylinder supplied arrangements were considered, but the details of the pipeline systems and their associated oxygen supplies were not assessed. When a cylinder was used at the bedside however, the whole system including the cylinder was assessed. The reason for these two approaches is that in pipeline supplied arrangements the ward staff have no real input to the management of the system beyond the wall port, while they have total responsibility when cylinders are in use (besides the central allocation of resources).

Although the research was focussed on ward based oxygen therapy, the movement of patients within the hospital and via ambulance was addressed as a special case of a 'mobile ward' environment.

Patients being cared for in the recovery area after surgery were also taken into account since it is a ward environment and almost all post operative patients have some oxygen therapy.

Intensive Care and High Dependency units were not directly assessed in this research since they have very different management systems compared to other wards. Patients are often mechanically ventilated and are cared for by highly trained staff on an almost one to one basis. There were however some overlapping issues and for this reason they were not completely excluded.

Operating theatres were excluded due to their highly specialist nature and because they are so far removed from a ward-like environment.

1.1.4 *The Need and Contribution of this Research*

A literature search for the use of hazard analysis methods in healthcare yielded little. Some work in the USA (Spath, 2003) and the Netherlands (Van Tilburg et al., 2006) has been undertaken in specialist secondary healthcare using Failure Modes and Effects Analysis, while work is beginning at Cambridge University (WARD et al., 2007) examining primary healthcare using a range of hazard analysis techniques.

Since the publication of two landmark documents in 1999 (Kohn et al., 1999) and 2000 (Department of Health Expert Group (Chairman, CMO), 2000), the number of publications on Patient Safety has increased dramatically. Figure 1-1 shows the results per decade of a search of the Scopus (Elsevier B.V.) database for items with the terms "Clinical Risk" or "Patient Safety" in the title, keywords or abstract, published between 1960 and 2007. A total of 9175 items were listed, with 81% (7414) published in the eight years from 2000 to 2007 and 47% (4272) of all items published in the three years from 2005 to 2007. Over

80% of the references found in Scopus were thus published since these key documents.

Only 19 references had the terms “Ward” and “Therapy or Therapies” in the title, keywords or abstract, with the oldest dating to 1994. Only 5 of these (Schmidt and Bottoni, 2003; Runciman et al., 2003; Daudelin and Selker, 2005; Croskerry et al., 2004; Agnoletti et al., 2005) dealt specifically with hazards or risks, all of which were between 2003 and 2007. Most address fairly specific issues and none employ structured hazard analysis methods.

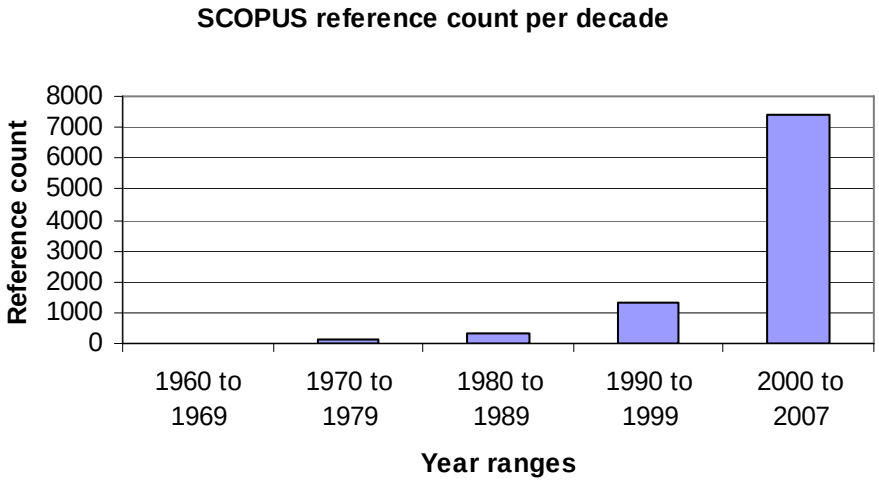

Figure 1-1. The number of publications from 1960 to 2007.

There is a recognition by respected professionals that ward based care constitutes a large proportion of adverse incidents (Nguyen et al., 2001b) and yet, despite a huge interest in patient safety, almost nothing has been published regarding hazard analysis and risk management of this area of healthcare.

This indicates a desperate need for an investigation of structured techniques for the analysis of patient safety on hospital wards. The value of this research is the provision of evidence to illustrate the need for tools to facilitate decision making and implementation of informed risk management strategies and protection against hazards.

The contribution of this research is twofold:

1. It addressed the issue of the apparent lack of techniques available for assessing hazards inherent in ward based therapies by testing a small number of established methods by application within this context. It discussed these ‘industrial’ prospective hazard analysis methods, taking account of the difficulty and value-added contribution of each by comparison to specially constructed evaluation data.
2. The trials and comparisons provided the first comprehensive analysis of the hazards and risks associated with the administration of oxygen therapy.

1.2 The Research Structure and Methodology

The validation of a hazard analysis method is concerned with testing the accuracy, precision and relevance of a method to a given subject (Kirwan, 1996)(Kirwan et al., 1997; Kirwan, 1997). The objective is normally to either endorse or reject its use. This requires a very structured approach and often entails the use of meticulous statistical analysis for the measurement of key parameters. Very detailed validation data is needed and multiple experiments should be conducted.

Such a validation process is not yet, to the author's knowledge, possible in the domain of ward based therapies. Attempting to produce accurate probabilistic assessments on risk likelihood is one area where such an endeavour might fail as there is scant data available for this type of analysis. Multiple experiments are difficult to arrange due to the heavy workload of most clinical professionals and may be prohibitively expensive.

This research was therefore concerned not with the validation of the hazard analysis methods, but to provide an evaluation in this specific context based on comparison to data produced through empirical research and basic risk analysis. This is the closest to a full validation possible given currently available data. The result might be used to help guide informed choice on hazard analysis methods and it may also be possible for it to have some use in future validation studies.

Inspiration was drawn from the methodology of evaluation and action research (Robson, 2002e; Breakwell and Millward, 1995) for both aspects of this project. The hazard analysis methods were evaluated for their effectiveness and relevance while the current practice in the application of oxygen therapy was evaluated for risk with a view to improvement.

This research is the first known attempt at the comparison and practical evaluation of these industrial prospective hazard analysis methods within ward based therapy.

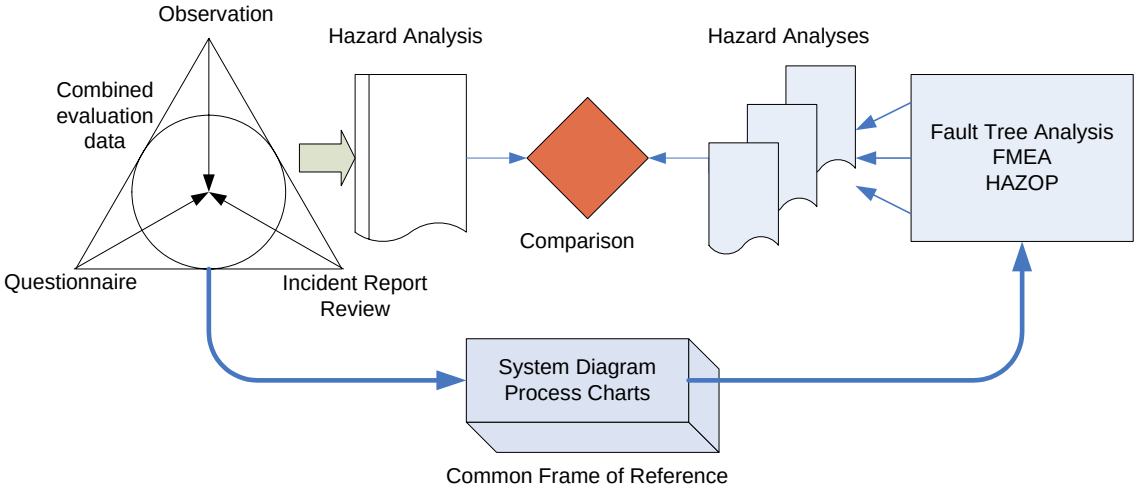

Figure 1-2. A flow chart representing the structure and progression of the project.

The structure and progression of the research can be seen in Figure 1-2. There were three phases:

1. The construction of a hazard analysis from the results of three empirical studies. These results were also used to produce a system diagram and process flow chart which formed the common frame of reference for the formal hazard analyses.
2. The application of three hazard analysis methods to a ward based therapy based on the common frame of reference produced from the research conducted in phase one.
3. The comparison of the results of the hazard analysis methods to the hazard list constructed during phase one. The methods were also compared to each other in terms of output, presentation of results and 'usability'.

Failure Modes and Effects Analysis (FMEA)(McDermott, 1996), Hazard and Operability Analysis (HAZOP)(Redmill et al., 1999b) and Fault Tree Analysis (FTA)(Ericson II, 2005c) were the prospective hazard analysis methods identified, following a structured selection process, as having the potential for application to ward based therapies.

The evaluation data was constructed as shown in Figure 1-3 by combining the results from an observational study and a health care 'practitioners' questionnaire. A structured review of NHS incident reports was used to validate the hazard list and amend it where necessary. It also provided a risk analysis from an alternative perspective.

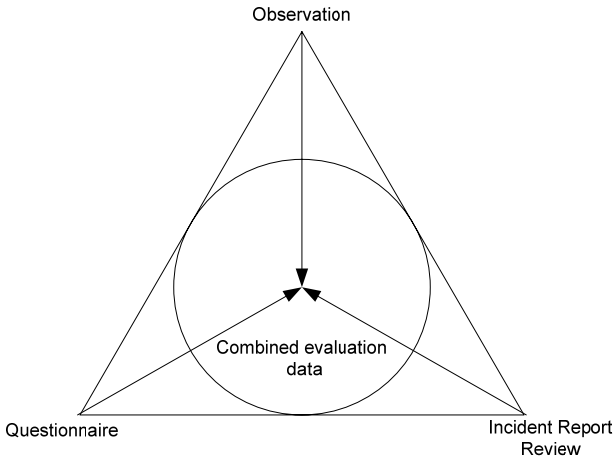

Figure 1-3. The construction of combined evaluation data from three empirical methods.

The hazard analysis methods were applied to Oxygen Therapy and compared in terms of their difficulty to use, presentation of results and the range of hazards analysed. The effectiveness and further contribution of the hazard analyses was assessed by comparison to the evaluation data and by discussion.

A final comprehensive hazard and risk analysis of Oxygen Therapy, combining all of the results, was produced. Only patient safety was assessed, even though hazards to staff also exist. The effectiveness of the therapy was only considered

if, as a result of some error, there was a failure to provide what was intended; the general clinical efficacy of the therapy was not assessed.

The research was conducted with the co-operation of two similar sized hospitals from different NHS Trusts. They are separated by approximately 40 miles (64 Kilometres) and were considered independent as they had no known formal relationship during this research.

A favourable ethics opinion for a multi site project was given by the Bedfordshire Local Research Ethics Committee on 11th May 2006 with a notice of substantial amendment receiving a favourable opinion on the 9th Nov 2007.

1.3 The Thesis Structure

The thesis structure is shown in Figure 1-4 and can be divided into five sections:

1. Introduction:

   Chapter one provides the background and description of the research, illustrates the thesis structure and states the contribution to knowledge.

2. Literature Review:

   Chapter two contains a literature review focussed on the subjects of Patient Safety, Hazard Analysis, Oxygen Therapy and Complexity.

3. Philosophy and Science:

   Chapter three discusses the subjects of methodology and methods and their relationship to this research, with an overview of the resulting choice of research methods.

4. The Research:

   Chapter four describes a ward based observational study and a questionnaire of healthcare professionals, a combined method used for the mining of hazards associated with oxygen therapy.

   Chapter five details a highly structured taxonomic study used to validate and amend the hazard list by review and analysis of reported incidents.

   Chapter six explores the use of Failure Modes and Effects Analysis, Fault Tree Analysis and Hazard and Operability Analysis, describing how these methods were evaluated and presenting the results and conclusions.

5. The Conclusion:

   Chapter seven, influenced by chapter one, provides a roundup of results, a discussion on whether the research questions have been adequately addressed and what the final answers were. The results specific to oxygen therapy are discussed along with

possible hazard barriers and risk management strategies as solutions to some of the issues identified.

Future work is identified, including a discussion on how this research might be extended to other therapies and processes.

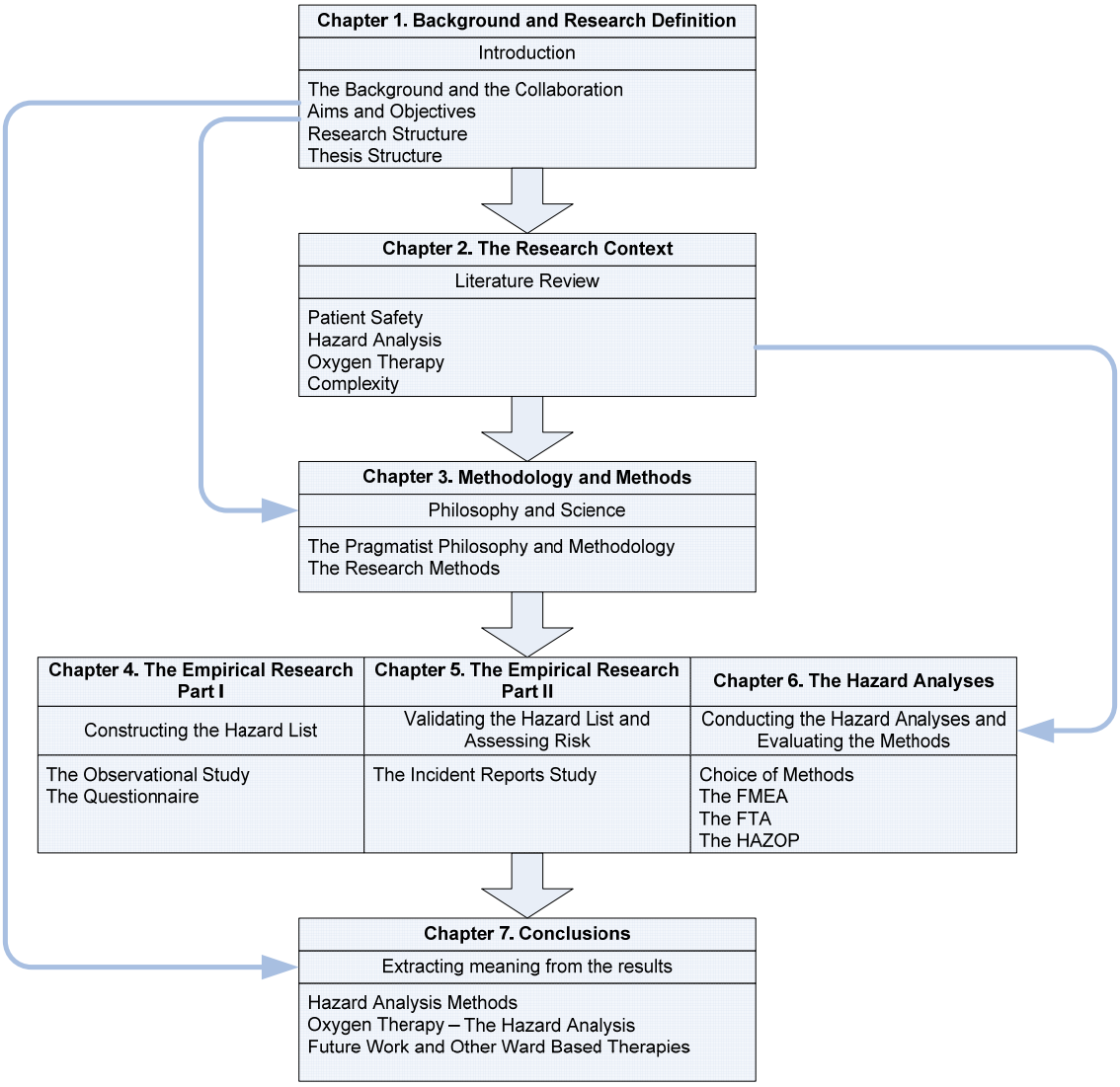

Figure 1-4. The thesis structure.

1.4 Conclusion

In the introduction to this chapter (Section 1.1.1, page 18), the objective of the research was stated as:

> *'To use evaluation data in the form of a validated, refined hazard list and risk analysis for the assessment of a small number of hazard analysis methods applied to a ward based therapy.'*

This then informed the research question:

> *'What is the contribution that formal hazard analysis can make to the assessment of patient safety within ward based therapies?'*

Based on this, the hypothesis was formed that a number of hazard analyses based on a common frame of reference, using formal methods, will produce comparable value-added results when tested against empirical research.

The research strategy outlined comprised of three phases. Phase one, during which a hazard list was constructed using empirical research methods, also produced the common frame of reference on which to base the three formal hazard analyses, which were conducted In phase two. The final phase involved the evaluation of these methods by comparison to each other and to the hazard list produced in phase one.

The background to this research was discussed, the scope defined and the need explored with reference to published literature. The contribution was identified as:

1. The research addressed the issue of the apparent lack of techniques available for assessing hazards inherent in ward based therapies by testing a small number of established methods by application within this context. It discusses these formal hazard analysis methods, taking account of the difficulty and value-added contribution of each by comparison to specially constructed evaluation data.
2. The trials and comparisons undertaken in this research provided the first comprehensive analysis of the hazards and risks associated with the administration of oxygen therapy.

Chapter 2 The Research Context

Abstract

This chapter explores the subjects of Patient Safety, Hazard Analysis, Oxygen Therapy and Complexity. These form the core context within which this research takes place.

Patient safety has evolved from a need for risk management in healthcare and the recognition of the importance of both high quality care and the wider implications of adverse incidents. Healthcare is now at a point where many of the lessons learned by industry can be applied; Prospective Hazard Analysis is one of them.

Seven hazard analysis methods from a total of over 100 were available to the researcher. These were FMEA, FTA, ETA, HAZOP, SWIFT, HEART and THERP. They are described and their previous use in healthcare is explored, with only FMEA, FTA, ETA and HAZOP having any published accounts.

Oxygen Therapy was used as the exemplar in this research and as such the various modes of delivery were explored and previous published work reviewed. There are numerous administration methods and variations of these, making many opportunities for error. Previous research into the administration of oxygen has focused on fairly specific subjects, while other work has been concerned with the physiological effects of the gas.

The complex nature of ward based therapies and where it fits into the system of healthcare is discussed in the final section. An influence diagram (Figure 2-8) graphically illustrates this complexity and the six principles of complexity and how they relate to this subject reinforce this concept.

2.1 Patient Safety

2.1.1 *The History of Patient Safety in the United Kingdom*

Under Crown Immunity, hospitals in the UK could not be prosecuted for incidents that occurred within their premises. When this was removed in 1990 (Centre for Corporate Accountability, 2003)(Steele, 2002; Chapman, 2001), individual professionals were covered under the new Crown Indemnity against negligence claims, but not against criminal prosecution. NHS trusts are now responsible for paying successful negligence claims, which they may not attempt to transfer to individuals they employ. To protect themselves from these claims, trusts are covered by indemnity insurance under the 'Clinical Negligence Scheme for Trusts' (CNST) which was set up in 1995 (NHS Litigation Authority, 2008a)(Walshe, 2001), with all claims handled by the NHS Litigation Authority (NHSLA) (NHS Litigation Authority, 2008b).

Risk management has, until relatively recently, been primarily concerned with protecting the organization against litigation. Part of the motivation behind many improvements is the resulting discount applied to CNST premiums. These discounts depend on the robustness of a Trust's procedures and systems, measured against CNST standards.

Jones, in chapter 6 of '*Patient Safety Research into Practice*' (Walshe and Boaden, 2006) is very keen to point out though, that the perceived relationship between costs from litigation and risk management is far less significant than expected(Jones, 2006). Jones states that even if improved risk management leads to better patient safety, that does not mean that there will be fewer claims or that they will cost less. The sheer volume of potential claims means that there is likely to always be a growth in successful claims.

> "*If there are 85,000 patients per annum who suffer injury as a result of negligence and only 7,000 claims (of which some 75 per cent may be unsuccessful) then if a risk management system was dramatically successful and reduced adverse events by, say, 50 per cent there would still be plenty of potential claimants, who currently do not make a claim, who could produce an increase in claims.*" (Jones, 2006)

A further motivator for improvement is the Clinical Governance framework by which trusts are assessed and awarded star ratings. In December 1997, The government published a white paper "*The new NHS: modern, dependable*" (Department of Health, 1997). In response, the Department of Health issued a consultation document entitled "*A first class service: Quality in the new NHS*" (Department of Health, 1998), in which the framework for clinical governance in the new NHS was outlined. These documents introduced the concept of clinical governance and stated the intention to establish the National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement.

NICE was set up in 1999 and was changed in the 2004 White Paper '*Choosing health: making healthy choices easier*' (Department of Health, 2004a) to the National Institute for Health and Clinical Excellence (NICE, 2009). NICE makes assessments of new drugs, treatments and devices as well as gathering information from the national confidential enquiries to produce standards and guidance for the provision of healthcare. The Healthcare Commission (formerly the Commission for Health Improvement) makes an annual assessment of NHS trusts and produces star ratings placing these trusts in a league table system. Continual improvement in quality of care and maintaining core standards is the responsibility of the Chief Executive for every trust, which provides some impetus from the top levels of leadership.

A growing awareness of Patient Safety within the Healthcare sector, resulted in the UK Department of Health report "*An Organisation with a Memory*" (Department of Health Expert Group (Chairman, CMO), 2000), which followed shortly behind another landmark publication by the Institute of Medicine in the United States; "*To Err is Human: Building a Safer Health System*" (Kohn et al., 1999). Both these documents had a substantial effect on how patient safety was perceived, with the emphasis changing from litigation avoidance to one where prevention of extended hospital stays and quality of care is strongly promoted.

Litigation was costing the NHS around £400 million in 2000(Department of Health Expert Group (Chairman, CMO), 2000; Jones, 2006), but the costs incurred in NHS hospitals due to extended hospital stays was estimated at about £2 billion per year, without taking into account the further economic costs(Department of Health Expert Group (Chairman, CMO), 2000). It is thus

more important to focus on the quality of care and patient safety as a combined package to reduce costs by minimising extended hospital stays rather than the cost of litigation alone.

Damage to reputation is an important aspect of any service industry and is set to become more so in the future of the NHS when patients are given more choice on where they receive treatment or care (Department of Health, 2004b)(Department of Health, 2007; NHS Choices, 2008). As stated in '*The NHS Improvement Plan: Putting people at the heart of public services*' (Department of Health, 2004b), quality will be a major factor in the informed decisions made by patients on where to go for their care, but the issue of reputation is only, almost subliminally, inferred. This is also only touched on in "*An organisation with a memory*".

> *"Stories about very poor care regularly hit the headlines and they worry people. They give the impression that the NHS is powerless to prevent such disasters and they generally undermine public confidence in services. Rightly or wrongly, accounts of particular health service failures lead to the perception that they may be only the tip of an iceberg beneath which much more poor quality lies."* An organisation with a memory (Department of Health Expert Group (Chairman, CMO), 2000)

This issue is not even directly addressed in the Department of Health report 'Choice matters: 2007-08 - Putting patients in control' (Department of Health, 2007), but there is a statement that makes it clear that there would soon be competition between NHS and private hospitals.

> *"From April 2008, patients referred by their GPs for most types of planned treatment will be able to choose from any hospital or clinic (i.e. any NHS trust, Foundation Trust, Independent Sector hospital or Independent Sector Treatment Centre) that can meet NHS prices and NHS standards."* Choice matters: 2007-08 - Putting patients in control.

The National Patient Safety Agency (NPSA) was set up in 2001 as a direct result of "*An Organisation with a Memory*" and was part of the UK government's plan to engineer a safer National Health Service. Their primary brief is to collect and analyse adverse incidents and near misses from NHS institutions with the aim of learning from them. This is done through the Reporting and Learning System (RLS)(NPSA, 2008b) and communicated via three routes: Patient Safety Alerts, Safer Practice Notices and Rapid Response Reports. Feedback reports are also available to NHS institutions and provide information specific to a particular trust, quarterly reports are available generally and provide summary information on incident numbers and trends. Until recently, newsletter style bulletins which contained commentary and articles relevant to current issues were also produced.

Since 2000 there has been a lot of debate about the best way to measure and improve patient safety in general. There are three key books which cover this subject, the first is edition two of '*Clinical Risk Management*'(Walshe, 2001) edited by Charles Vincent. This is an essential text for those wishing to gain an in depth insight into the subject of clinical risk management, including its history in healthcare, with contributions from most of the key people in the field. The

two further texts, ‘Patient Safety’ by Charles Vincent(Vincent, 2006b) and ‘Patient Safety Research into Practice’ edited by Kieran Walshe and Ruth Boaden (Jones, 2006) both bring the subject up to date from two rather different but complimentary points of view. Walshe and Boaden provide a structured exploration of current research and the avenues for improvement in practice, while Vincent gives a stimulating discussion of the major themes and illuminates the possible paths the subject might still take.

The patient safety agenda became international with the launch on 27 October 2004 of the World Health Organization’s ‘*World Alliance for Patient Safety*’ (WHO, 2009), currently chaired by Sir Liam Donaldson, Chief Medical Officer for England. Their ambitious plan for 2006-7 set out in their ‘*Forward Programme 2006-2007*’ (World Health Organization and World Alliance for Patient Safety, 2006) details the ten areas of action they have undertaken.

It is therefore clear that clinical governance and patient safety play key roles in the continued improvements in quality of care and patient choice being introduced by the Department of Health in the UK. These factors cannot be separated completely as improvement in one affects the other. Being in the position to clearly identify hazards to patient safety and implement barriers to prevent harm will thus have a positive effect on quality of care and provide clear evidence for sustained clinical governance. This would in turn place an institution in a better position to be chosen by patients for their care and treatment and promote patient satisfaction.

The National Audit Office (NAO) publication “*A Safer Place for Patients: Learning to improve patient safety*” in November 2005(National Audit Office, 2005) stated that 974,000 adverse events were reported during 2004/5 and that 2,180 of these were reported to have resulted in death. These figures compare well with those extrapolated from results reported by Vincent and colleagues (Vincent et al., 2001) in their pilot study to assess the extent of the patient safety problem in the UK. They concluded that approximately 10.8% (918,000) of the 8.5 million patients admitted to hospital every year experience adverse incidents and that 8% (73,000) of these might lead to death. The large difference in the number of deaths between the two publications can likely be attributed to a range of factors including: Under-reporting of serious events affecting the National Audit office figures, differences in the classification of harm (especially by those reporting the incident), the exclusion of hospital acquired infections by the National Audit Office publication and the inclusion of contributory factors leading to death in the work by Vincent et al (2001).

In March 2000, the British Medical Journal (BMJ) published a themed issue on patient safety that had a strong focus on human error and reliability. It included a very insightful editorial by the eminent Lucian Leape and Donald Berwick (Leape and Berwick, 2000), which is reported as having been cited 83 times in Scopus. Their comment on the contents of that issue of the BMJ also provides something of an overview of the state of the art of patient safety in 2000. Leape and Berwick comment on what is known on the subject and acknowledge the breadth of knowledge contained within healthcare that would be useful to the improvement of patient safety if it was properly used.

> *"We have learnt that the problem of medical error is not fundamentally due to lack of knowledge. Though clearly we have much more to learn about how to make our systems safe, we already know far more than we put into practice."* BMJ, March 2000 (Leape and Berwick, 2000)

Taking proper notice of the views and opinions as well as the qualified judgments of high calibre healthcare professionals is paramount to this cause.

Although much has been done generally in the domain of patient safety since 2000, e.g. the establishment of the National Patient Safety Agency, not much has changed in healthcare practice on hospital wards that could be attributed to these efforts. It is quite obvious from this apparent lack of progress that the task is more complex and difficult than it would at first seem (Vincent, 2006b).

James Reason speaks quite plainly in that same issue of the BMJ about the 'person centred' approach to human error prevalent in the health service(Reason, 2000), which attributes the causes for incidents on the actions of individuals. This paper, cited over 500 times in Scopus, makes clear that there needs to be a shift from the person centred approach to a systems approach, where human error is seen as a failure of the system to account for how people perceive their tasks and environment, something that appears to be very slow in coming.

> *"Health care alone refuses to accept what other hazardous industries recognized long ago: safe performance cannot be expected from workers who are sleep deprived, who work double or triple shifts, or whose job designs involve multiple competing urgent priorities."*(Leape and Berwick, 2000)

> *"The pursuit of greater safety is seriously impeded by an approach that does not seek out and remove the error provoking properties within the system at large."*(Reason, 2000)

Reason makes a very strong case for the health service to learn from high reliability organizations like the US Navy, nuclear fuels and air traffic control centres. Nolan gives some examples of the use of reliability engineering in systems such as automated teller machines and discusses how these approaches might be employed in healthcare (Nolan, 2000). The use of automation is advocated only as a means of supporting and improving human reliability and there is an emphasis on error detection as well as prevention.

Many of the errors in systems with a high level of technology occur either at the human – machine interface(Lin et al., 2001) or are due to 'latent errors' introduced through imperfect design (Reason, 1999b), both are difficult to detect. Adding more technology is therefore not always the answer and can indeed introduce unexpected complexity. No system is perfect and to assume such is unrealistic, therefore a pre-emptive approach to error identification and prevention has much to commend it.

Public concern over the safety of patients on hospital wards is high. Currently the focus is on hospital acquired infections with many newspaper and television articles devoted to this topic. A search of just the '*Times Online*' produced numerous examples (BBC NEWS, 2006; BBC NEWS, 2005b; BBC NEWS,

2005a; Hawkes, 2007; Rose, 2007), including the following quote from an article entitled "*Blundering hospitals kill 40,000 a year*" (Woolcock and Henderson, 2004), in which the problem of care on wards is highlighted and mention is made of one problem with incident reporting; that not all incidents ever get reported.

> "*Approximately 25 per cent of errors occur during surgery, and another 25 per cent in diagnosis or pre-care.* ***The other half of all mistakes are made during treatment on the ward****. They can range from providing patients with inadequate nutrition to prescribing the wrong dose of medication.*
>
> *The figures do not include any hospital-acquired infections or complications of childbirth, and almost 10 per cent of the trusts surveyed claimed an unlikely error rate of zero.*
>
> *"It shows there is not enough transparency," Mr Taylor*[1] *said. "Sometimes no one ever finds out if a patient died as a result of something going wrong — it may never go outside the group involved in that patient's care.""*

The article was reporting a study by Aylin et al, which looked at the incidence of the recording of adverse events within hospital episode statistics (Aylin et al., 2004). This study did not look at death as a criterion, nor was it reporting on this. The 40,000 deaths a year comes from the first line of the article, which refers to a presentation at the ISO General Assembly 2001, Sydney (Emslie), which was used by the authors to illustrate the need for better methods of collecting and using this type of data.

In 2001, Nguyen wrote in a letter (Nguyen et al., 2001a) responding to a publication by Vincent et al in the same year (Vincent et al., 2001) that "*Most [serious] adverse events have their genesis in general wards…"*, and went on to call for more work to be done on finding solutions. It would be logical to add that we should be looking for ways to identify and manage hazards in the hospital wards where it seems the bulk of incidents occur.

[1] Roger Taylor, research director of healthcare research group, 'Dr Foster'.

2.2 Hazard Analysis Methods in Industry and Healthcare

Formal hazard analysis methods allow those responsible for design, planning or management of products, systems or processes to understand how these can fail (before they do) and to take steps to prevent this or mitigate the consequences.

It was previously rare for formal risk assessments to be used in healthcare for the planning or management of treatments and ward based activities, with virtually no risk management in place in the UK until the late 1980's (Walshe, 2001). Risk assessment is now routinely used in the NHS for complex decision making on issues like surgery or the aggressive treatment of serious conditions, but little is done for more routine processes.

As matters have progressed, the need has arisen for a more structured approach covering more aspects of the patient experience in a prospective, preventative manner. The NHS, as directed by the Department of Health (Department of Health,Sir Ian Carruthers OBE and Pauline Philip, 2006; Department of Health, 2002) and advocated by the NPSA (National Patient Safety Agency; National Patient Safety Agency, 2006), has begun to make use of hazard analysis as a means to address this. Since most prospective hazard analysis methods remain untried in a healthcare setting, this evaluation was undertaken to fill this need.

There are over 100 methods for hazard analysis in existence (Lyons et al., 2004). Many are variations of each other, but even when this is considered, there are still numerous techniques available. In his book 'Hazard Analysis Techniques for System Safety' (Ericson II, 2005c), Ericson details 22 that are often used, mainly in heavy industry. There are others regularly used in the 'softer' side of many industries (e.g. customer services), that are not included in Ericson's book.

Seven techniques generally considered as well established within industry and presented at training courses held at Cranfield University (Tetlow et al. 2005) and at an external seminar (Boult et al., 2006) were considered for this research. They were all accessible to the researcher and expert knowledge on most of these was available on campus. A brief description of each follows, including any previous applications in healthcare. More detailed explanations and in depth discussions are available in Redmill (Redmill et al., 1999b), McDermott (McDermott, 1996) and Ericson (Ericson II, 2005c). Some further description of three of these is also provided in chapter 6.

2.2.1 *Failure Modes and Effects Analysis (FMEA)*

FMEA is described as an inductive[2] method best suited for use as a detailed design technique (Ericson II, 2005b)(McDermott, 1996). It is useful for evaluating the effects of individual failures, but does not consider the effects of multiple failures.

FMEA is capable of analysis down to system component level and can be generally applied; although it is more commonly used for device design or manufacturing process analysis (Arvanitoyannis and Varzakas, 2007). In normal practice, process assessments are undertaken separately from the analysis of physical system components. The results are presented in tabular form and include a Risk Priority Number (RPN) based on a 'three dimensional' risk assessment of '*Likelihood*', '*Severity*' and '*Detection*' of each '*Failure Mode*'.

Failure Modes and Effects Criticality Analysis (FMECA) is a slightly extended version of FMEA, with the additional assessment of the criticality of a failure to system reliability.

There has been some application of FMEA in healthcare, and its use is advocated by organizations such as the Joint Commission (The Joint Commission, 2008), the Healthcare Commission and the NPSA. It has been applied in the assessment of the use of infusion devices(Fechter and Barba, 2004) and is described by Spath in ways more generally applicable to healthcare(Spath, 2003). Dhillon describes its use in the design of medical devices, paying particular attention to the consideration of human error(Dhillon, 2000).

It has been modified and used in healthcare by the Veterans Association in the USA, who renamed it '*Healthcare FMEA (HFMEA)*'. DeRosier et al mention in a publication describing HFMEA(DeRosier et al., 2002) that an assessment of FMEA was made, but their evaluation is not described and very little is provided on the outcome. HFMEA has been used to assess children's oncology in the Netherlands (Van Tilburg et al., 2006) and the sterilization of surgical instruments(Linkin et al., 2005).

---

[2] Inductive and deductive refer to types of logic {{389 Ericson II, Clifton A. 2005; }}.

Deductive reasoning is fact based and relies on the truth of a premise. It assumes an error has occurred and further analysis is based on known effects. Inductive reasoning is based on a wider premise and is more probabilistic in nature. It is less rigid, asking questions like 'if this fails, what might happen?'

2.2.2 *Fault Tree Analysis (FTA)*

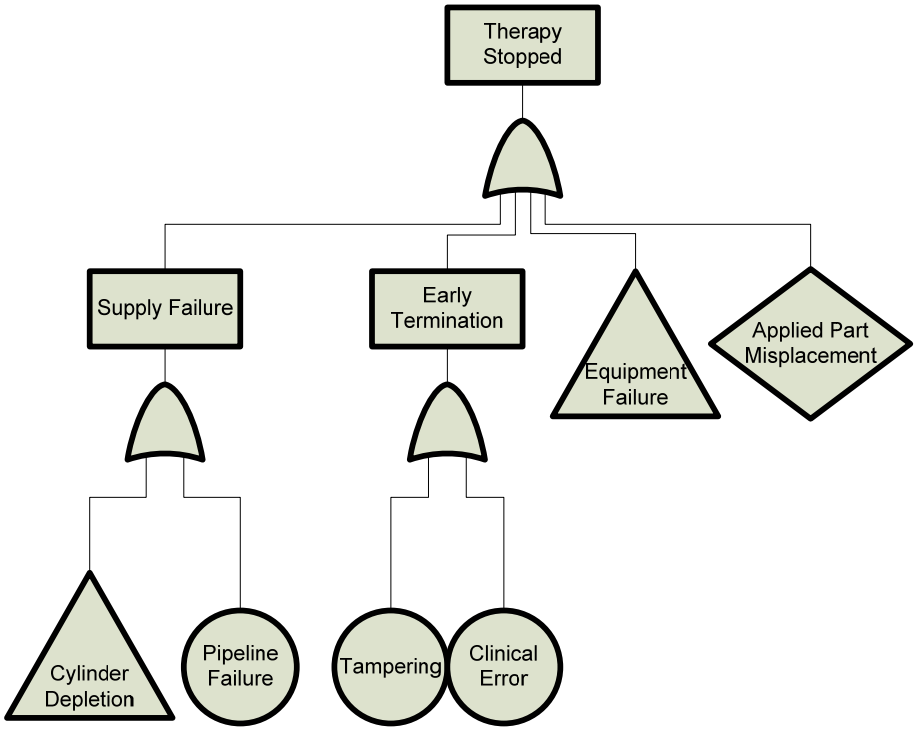

Figure 2-1. An example of part of a Fault Tree applied to oxygen therapy.

FTA is, according to Ericson, a deductive method in the 'system design hazard analysis type' category (Ericson II, 2005b). The final result is mainly graphical in the form of a gated logic tree as in Figure 2-1, but can also include quantitative, probabilistic analysis.

One of the results of an FTA is the production of '*Cut Sets*', which are the minimal failures that can cause an adverse event and '*Tie Sets*', which are the minimal conditions required for a functional system. Unlike FMEA, FTA is particularly useful for identifying multiple cause events and cascade failures, in which an initiating event causes a series of failures, one triggering the other.

Fault trees have been used as part of '*root cause analysis*' for the investigation of adverse events within healthcare for some time(Vincent, 2006b; National Patient Safety Agency). Their focus when applied in this way is retrospective and limited in scope to the event under investigation. No specific use of prospective FTA in a healthcare setting could be found in the literature, but some general comments on its use can be found in various places(Durand et al., 2007), most notably on the National Patient Safety Agency website(National Patient Safety Agency) and a discussion by Dhillon on its use for assessment of the reliability of medical devices(Dhillon, 2000).

2.2.3 *Event Tree Analysis (ETA)*

ETA is also a deductive, mainly graphical method(Ericson II, 2005b). It focuses is on the events leading to an adverse event and the effect of barriers or contingencies. Figure 2-2 is an example of an Event Tree in both its generic descriptive form (top tree), and how it might be applied to one aspect of oxygen therapy (lower tree).

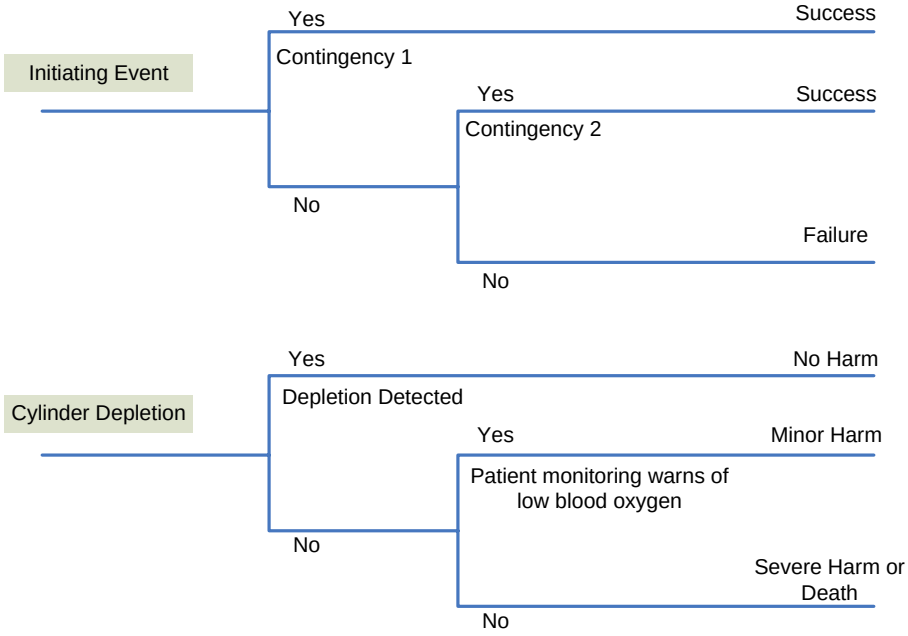

Figure 2-2. Example of an Event Tree

A range of outcomes can be included to give a very thorough analysis of event sequences. Probability information can be added to the tree at each event branch, but these sometimes have a large element of uncertainty (Gressel and Gideon, 1991), especially in areas such as healthcare. It is possible to transcribe the tree into a tabular notation which focuses on the failure pathways and thus minimises the tree.

Only one example of the use of Event Trees in healthcare could be found which focussed on the assessment of cardiac services in ambulances (Stoykova et al., 2004).

2.2.4 *Hazard and Operability Analysis (HAZOP)*

HAZOP is both a deductive and an inductive method with a tabular format (Redmill et al., 1999a). Ericson places it in the preliminary and detailed design hazard analysis type categories (Ericson II, 2005b), making it an extremely versatile method. Developed by ICI in the 1970's, HAZOP is applicable to many situations, including device, task or process analysis, but it is mostly used for process analysis. It is a team based method requiring a multidisciplinary panel of experts to provide input. It is based on the use of word models, applying guidewords to system or component attributes to describe possible deviations from intent. The results are presented in a tabular form with columns containing the hazard identification, the applied guideword, a description of the deviation,

the possible causes and the possible consequences. It also contains risk management information such as safeguards that might prevent an incident and a list of the actions necessary to put these in place. HAZOP is not supposed to be a one-off technique, but was designed to be a complete risk management system with feedback routes enabling constant updating of the assessments and risk management strategies (Redmill et al., 1999a). The technique is very useful during a design process for identifying hazards so that they can be "designed out".

No published reference to the use of HAZOP in any healthcare setting was found. Indirect reference was found as described by Redmill (Redmill et al., 1999b). It is not clear why HAZOP seems unpopular, but it may be due to it being perceived as a purely engineering design method while methods which appear similar, like FMEA, have been used in a variety of applications from an early stage. It may also be that HAZOP is often seen as being very similar to FMEA, whereas the two are in fact quite different and complimentary (Redmill et al., 1999b). It is not unusual to find an FMEA, FTA or ETA within a HAZOP to clarify points of detail, causality or effect.

2.2.5 *The 'Structured What-If Technique' (SWIFT)*

SWIFT is a very creative, inductive method with both a graphical and a tabular outcome (Boult, 2006). What-if techniques of various types have been used widely in industry and are particularly suited to the construction of computerised expert decision support software (L. Fortuna, S. Graziani, M. G. Xibilia,G.Napoli, 2006; Thereska et al., 2005; Philippakis, 1988). SWIFT models can be drawn as event trees or entered into worksheets similar to those used in FMEA. The process involves brainstorming a topic to identify hazards which are then explored in sequence using 'what-if' questions to identify both causes and consequences (Anglia Ruskin University). Checklists constructed from a hazard list are used to ensure all identified hazards are examined and that no duplications occur.

No specific examples of the use of SWIFT in healthcare and very little instructional literature could be found.

2.2.6 *Human Error Assessment and Reduction Technique (HEART)*

HEART is an inductive method with a tabular result designed for application to human factors only (Williams 1986). It does not identify hazards, but rather uses a numerical method to assign human error probabilities (HEPs) to events identified by task analysis. No published examples related to healthcare could be found.

2.2.7 *Technique for Human Error Rate Prediction (THERP)*

THERP is also used to assess only human factors. It uses a similar numerical method to HEART, but is more prescriptive in the task analysis categories used. Use is also made of an event tree and the associated algebra to assign probabilities and weighting factors to events. As with HEART, no published examples relating to healthcare could be found.

2.3 Oxygen Therapy

2.3.1 *Description*

Oxygen therapy is the practice of administering oxygen at concentrations higher than normal air to a patient for the reasons of:

1. Alleviating symptoms of a condition affecting their ability to make full use of the 21% concentration of oxygen found in air. Examples include Asthma or dyspnoea (Nicola Cooper, 2004; Thomas, 2005) and Chronic Obstructive Pulmonary Disease (COPD)(Plant and Elliott, 2003; Wouters, 2004; Durrington et al., 2005).
2. Attempting to prevent the possible onset of complications after surgery by pre and peri-operative oxygen supplementation (Belda et al., 2005; Kabon and Kurz, 2006; Weissman, 2005).

The supply source is either a free standing cylinder, or a piped supply delivered to an outlet port on the ward. Pipelines are fed from a Vacuum Insulated Evaporator (VIE) or banks of cylinders. Flow is set by the use of an indexed fixed orifice selector or a combined flow meter and needle valve restrictor. Flow meters used in this application are usually Thorpe Tube rotameters of the type depicted in Figure 2-3.

Figure 2-3. Thorpe Tube Flowmeter. 0 to 15 lpm at 60 Psi (4bar).

From Therapy Equipment Ltd Specification sheet available at http://www.therapyequipment.co.uk

Humidifiers should be employed when the flow rate is higher than about 2 Litres per Minute (Lpm), or if therapy is administered over prolonged periods. These are normally simple bubble humidifiers (White, 2004a). The guideline at Bedford Hospital states that the therapy should be humidified after a patient has received general anaesthetic or requires more than 28% of oxygen.

Tubing is used to conduct the oxygen to a patient connected device such as a face mask or nasal cannula (also known as prongs or specs). If the therapy is not to be humidified, a standard tubing set of 1.5m to 3m long and internal diameter of 5mm can be used. If the therapy is to be humidified, 22mm

diameter tubing must be used to prevent water being forced into the tube thus creating a drowning or tube occlusion hazard.

Nasal cannulae are simple hollow tubes with prongs that insert into the nostrils. Figure 2-4 shows a typical example. Nasal cannulae produce a variable concentration of oxygen that depends on the oxygen flow rate and the breathing characteristics of the patient. They can easily become blocked by nasal discharge and often cause irritation to the ears, nose and upper lip. If a patient breathes through the mouth, very little supplemental oxygen will be taken into the lungs. They allow the patient to talk and eat normally and can be worn while asleep.

Figure 2-4. Nasal cannula.

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Figure 2-5 is an example of a simple face mask, also known as a Hudson mask. This device also produces a variable oxygen concentration dependent on flow rate and breathing. Some people find them uncomfortable or completely intolerable. They become dislodged easily and cannot be comfortably worn while sleeping. Talking is difficult and eating or drinking is impossible.

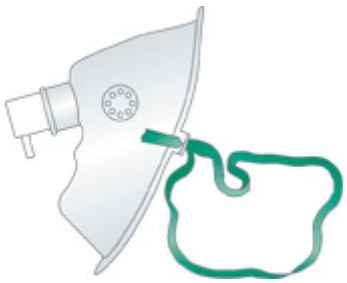

Figure 2-5. Simple or Hudson mask.

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Figure 2-6 is an example of another variable concentration mask. This type is usually called a non-rebreathing mask, trauma mask, or sometimes a reservoir-bag mask. They are used when a high concentration of oxygen up to approximately 90% needs to be delivered. These mostly overcome the dead space problem with the Hudson mask by using a series of one way valves and a reservoir of oxygen from which the patient can draw. They are however, still a variable concentration device.

In order to give high concentrations of oxygen, the flow of oxygen to the bag needs to be higher than the volume breathed in by the patient per minute (Minute Volume). The bag needs to be refilled during the time the patient is breathing out (expiration). For this to happen, the flow of oxygen needs to at least equal to:

$$\text{The volume breathed in (Inspired Tidal Volume)} - \frac{\text{Oxygen Flow}}{\text{Inspiration time}}$$

Equation 2-1. Calculation of minimum flow rate for reservoir bags.

Due to the one way valves, there is a danger of severely increasing the work required for breathing if too little oxygen is flowing to refill the bag.

Figure 2-6. Non-rebreathing mask.

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When a more accurate oxygen percentage is required, a ‘venturi’ mask is used, as shown in Figure 2-7. These can give up to 50% oxygen at high flow rates, which eliminates the problem of re-breathing by expelling all expired gasses from the mask. These masks work on the Bernoulli principle to generate an increase in flow rate and the viscous shearing effect (White, 2004b) to entrain air to mix with the injected oxygen.

Figure 2-7. Venturi mask.

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2.3.2 *Hazards*

The two most significant adverse outcomes for patients receiving oxygen therapy are hyperoxia (too much oxygen) and hypoxia (too little oxygen).

Hyperoxia affects only a small proportion of patients; neonates and those with CO_2 retention. Hypoxia affects everyone, but those with a high need for supplemental oxygen are at greater risk.

If one considers the old saying "it's not the fall that kills you, it's the sudden stop at the end", then hypoxia and hyperoxia are analogous to the sudden stop. It was however, the hazards that form the reasons for the “fall” which were of most interest in this research.

A hazard is defined by Ericson as “*Any real or potential condition that can cause injury, illness or death to personnel; damage to or loss of a system, equipment or property; or damage to the environment (MIL-STD-882D). A potentially unsafe condition resulting from failures, malfunctions, external events, errors or a combination thereof (SAE ARP-4761).”*(Ericson II, 2005a) In the context of this research, these are a range of errors and failures which often combine to construct the events that create an incident.

Human error has been the focus of much of the research in the area of oxygen therapy, with some studies looking at the way in which accessories are used (Small et al., 1992)(Attia et al., 2004; Cooper, 2002; Gravil et al., 1997), while others have explored the use of patient monitoring (Al-Mobeireek and Abba, 2002), prescriptions (Dodd et al., 2000) or the effects of training and guidelines (Akbar and Campbell, 2006; Kor and Lim, 2000).

Latent errors (Reason, 1999b) are those made at a higher level in a system and can remain dormant until specific conditions are met. They form one of a number of external factors and are usually innocently made management decisions affecting systems such as purchasing or operating procedure. The purchase of a particular brand or type of consumable, combined with the omission of another, may place a patient with a rare condition at risk. A decision on ward layout may mean that a particular bed space may have no piped supply and has to rely on cylinders; which places that patient at risk of cylinder depletion. Latent errors also include poorly written or erroneously compiled

protocols or guidelines, which may be more hazardous than having no guidelines at all.

2.3.3 *Hyperoxia*

If caught quickly many complications are reversible, but permanent lung injuries are possible and retinal damage is especially likely in preterm infants. Most of the literature involving hyperoxia is to do with premature infants who are given high doses of oxygen. This group of patients can be affected by a condition called '*Retinopathy of Prematurity (ROP)*', previously known as '*Retrolental Fibroplasia*' or '*Terry's syndrome*'(Patz 1975). The blood vessels in the retina are affected which causes retinal detachment. The retina is then converted to a fibrous retrolental (behind the lens) membrane.(CJ et al., 1997; Harling et al., 2005; Hay and Bell, 2000)

Incidents where oxygen therapy exacerbated breathing problems affecting paediatric patients have also been reported (Berger et al., 2000). Death is possible but is thought to be mostly as a result of complications caused by the resultant injury, or the patients' existing condition, rather than the injury itself.

Various problems can result from hyperoxia in adults. The one which appears to be of most concern is 'o*xygen induced hypercapnia',* which seems to have a number of causes. It is probably some combination of the following and possibly more: Constriction of vessels in the lungs as a response to high levels of Oxygen causes a change in the way gasses are perfused in the lungs, and partial pressure of CO_2 in the blood rises as a result. Reduced ventilatory drive and hence low minute ventilation is a further possible contributory factor (Calverley, 2000).

Another problem exists where a combination of elevated O_2 and too little CO_2 in arterial blood can cause an over-reactive constriction of the cerebral blood vessels. This can cause dizziness, confusion, convulsions and lack of consciousness until the balance is restored (Cooper, 2004).

The Haldane effect contributes when haemoglobin is saturated with Oxygen. The molecule's ability to carry CO_2 is therefore reduced, causing elevated levels of free CO_2. (Van Wynsberghe et al., 1995b) This in turn means that there is an increase in the number of hydrogen ions in solution, which may have an effect on a number of chemical balances in the gas transport mechanism.

Nitrogen is required as a medium for maintaining the inflation of the alveoli in the lungs. If 100% oxygen is used for too long, the nitrogen is expelled and the alveoli can collapse, causing absorption atelectasis (collapsed lung).

Patients with Chronic Obstructive Pulmonary Disease (COPD) appear to be the adult group most at risk to hyperoxia. A few of these patients have a high baseline CO_2 level to which their physiology has adapted. This means that they rely on the hypoxic drive mechanism to increase their respiratory rate. If they then receive a high concentration of oxygen which pushes their levels of oxygen over a threshold specific to them, their respiration rate falls and they can experience type two respiratory failure.

Some clinical scientists claim that inspired oxygen concentrations of as low as 24% can be dangerous to these patients, and advise that it is better to maintain a blood Oxygen saturation of 87% to 92% in patients with COPD rather than to aim at the more usual 98%(Plant and Elliott, 2003).

Most agree that these patients are very rare and that the advantages of applying oxygen outweigh the possible adverse effects. There is also the argument that since oxygen therapy is applied in a clinical setting where prompt action is possible, it should be given in all cases (Benditt, 2000).

Oxer seems to make light of the risks to some patients of having too much oxygen, describing the hazard as “myth” (Oxer, 1999). Oxer strongly criticises the various authorities for giving the impression that supplemental oxygen is an advanced, skilled procedure that requires special training, thereby discouraging some people from using oxygen in emergency situations. Numerous studies are sited that show the benefit of oxygen therapy, but none that conclusively prove there to be any major risk.

The main thrust of Oxer’s paper is that during resuscitation following cardiac arrest, as much oxygen as possible needs to get to the alveoli in order for there to be a good chance that hypoxic tissue will become re-oxygenated. The breath of someone giving expired air resuscitation (mouth-to-mouth) contains only 16% oxygen at best. It is easy to follow the reasoning that a face mask capable of delivering a flow of oxygen to increase the amount available to the patient during resuscitation can only help give them a better chance of survival.

2.3.4 *Hypoxia*

The problems associated with hypoxia (too little inspired oxygen) and hypoxaemia (too little oxygen in the blood) are well known. Hypoxia can cause permanent brain damage or death after only a few minutes. Sometimes, when the hypoxic event occurs at birth or soon after, the damage is difficult to asses and is only evident under extreme diagnostic procedures such as Magnetic Resonance Spectroscopy (Gadian et al., 2000). It would appear however that if no symptoms are present at 18 months, that no further significant problems are likely to occur later (Kjellmer et al., 2002). The consequences are however more often catastrophic in everyone; hypoxia is definitely to be avoided.

There are some patients who are at a higher risk due to an increased likelihood of hypoxia. Ventilatory responses are adversely affected in patients who are receiving or taking opiate drugs like morphine or heroin, which can lead to respiratory rate changes and hypoxia (Teichtahl et al., 2005). Patients with asthma, COPD, bronchitis or other lung infections are at high risk of hypoxia if oxygen therapy is interrupted.

There are also some special cases. Weinberg et al describe the factors which affect the care of the pregnant trauma patient (Weinberg et al., 2005). The trauma team have, in effect, two patients to deal with. Pregnant women are less tolerant to sudden changes in available oxygen, and care must be taken to protect mother and child. The functional residual capacity of a pregnant woman at term is reduced by about 20% due to the enlarged uterus pushing the diaphragm up into the chest cavity. This combined with the increase in oxygen

consumption of ‘both patients’ predisposes pregnant women to rapid desaturation.

2.3.5 *Prescription and Administration*

It has long been known that oxygen is not well prescribed by doctors, especially when compared to other medications. Small et al (Small et al., 1992) conducted a study in 1990 of the use of oxygen compared to antibiotics in a general hospital in the United States of America. It was discovered that approximately 28% of patients were having oxygen therapy and had oxygen therapy noted in their nursing and medication chart without a doctors’ prescription. They also noted that there was oxygen therapy equipment in the rooms of approximately a further 18% of patients without a prescription and no note made in the nursing chart. It is not clear whether this equipment was in use at the time, but its presence implies that it may have been in use at some time. There was no mention of instances of antibiotics being used without a prescription.

Oxygen therapy is not always well administered and is often poorly monitored. Small et al (1992) noted that in 34% of cases where patients had been prescribed oxygen, the oxygen supply was found to be turned off. They also found that face masks and cannulae were incorrectly worn in 57% of cases.

There appeared to be far fewer cases of misadministration of antibiotics, but the limitations of the comparative study must be considered. For example; they do not know that the nurses administered the antibiotic correctly, only that they wrote on the chart that they had administered it. It is perhaps impossible to tell if a patient has received antibiotics without a prescription and without a note in the nursing chart.

This is partly acknowledged by Small et al (1992), who made the assumption that the notes on antibiotics administration on the patients nursing chart were correct. The cooperation of the patient is also required. Together, these points make a comparison very difficult, and only loosely relevant. It does however serve the purpose of illustrating that there is a lack of care in the use of oxygen.

It might be argued however that antibiotics are more likely to cause adverse reactions, making staff more cautious in their use. Antibiotics are also more strictly monitored through procedure and by pharmacists and thus less likely to be misused.

The chart system for the notation of drug dispensing widely used on wards may not be very appropriate for the setting up or monitoring of oxygen therapy. Dodd et al (Dodd et al., 2000) conducted two audits of prescriptions of oxygen therapy in the North West Lung Centre in Manchester in the UK during 1997 and 1998. One was done before and one after a prescription chart specifically for oxygen was introduced instead of the standard form.

They found after the first audit using the original chart that only 55% of patients having oxygen therapy had actually had it prescribed. They also found that only 7% of prescriptions were accurately written out. The accuracy of prescriptions improved after the new chart was introduced, going from 7% to 94% for those patients with the new chart and to 63% for those still with the original.

Akbar et al discovered in a similar audit of a teaching hospital in the UK during 1999, that only 30% of patients had been accurately prescribed oxygen therapy (Akbar and Campbell, 2006). This compares well with Small et al (1992).

2.3.6 *Guidelines*

An extensive search for guidelines on the administration of oxygen therapy was undertaken, but very little was found on this subject. Local guidelines were available on the intranet site of one hospital in the study and a guideline produced by the American Association for Respiratory Care was found (Kallstrom 2002). This guideline is not very detailed and gives no advice on assessment of cylinder content or the need for humidification.

During their study, Akbar et al (2006) implemented new guidelines on oxygen prescription. They found that doctors' prescription practices did not change after implementation of new guidelines, but that nurses did improve their practices.

The studies by Dodd et al (2000) and Akbar et al (2006) show how different professional groups are affected by different strategies. Nurses appear more likely to be influenced by guidelines, whereas doctors were not influenced to any significant degree. Doctors and nurses were however both influenced by a new prescription chart.

Guidelines are thus not enough on their own. If not used or badly constructed, they can be detrimental and need to be backed up with policy to encourage good practice. Alan McLenaghan, Managing Director of Saint-Gobain Glass, UK said in an article on page 22 of the December 2007 issue of 'Engineering and Technology':

> "*If you ask me, while company policies don't act as motivators, a distinct lack of or poorly formulated policies can very quickly demotivate people*."

Kor and Lim also found a significant number of cases where masks and cannulae were incorrectly worn (Kor and Lim, 2000). More importantly, they found that 78% of patients were receiving inappropriate therapy; 3% were getting too little oxygen, while 75% were getting too much. This was so even after an educational programme to encourage the use of oxygen saturation monitors.

Al-Mobeireek and Abba also found deviations from prescriptions and inappropriate use of oxygen therapy in two hospitals in Saudi Arabia (Al-Mobeireek and Abba, 2002). This and the study by Kor and Lim (2000) were also concerned with cost saving; they both mention the excessive amount of oxygen used. A 63% reduction was possible in the case of the study by Al-Mobeireek and Abba (2002).

2.3.7 *Clinical Concerns*

Many studies have been carried out to examine the effects of oxygen in terms of the human physiology, or a particular disease or condition (Berger et al., 2000; Bitterman, 2004; Cohn, 2001; Fisher, 1980). Many of the clinical risks are known, especially relating to high risk patient groups like those with Chronic Obstructive Pulmonary Disease (COPD)or the very young (Patz 1975; Hay and

Bell, 2000; Cohn, 2001; Reedy, 2004). The advantages for the very ill are also known, and likely outweigh the risks when it comes to the decision on whether to administer oxygen (Benditt, 2000).

Benditt presents many of the clinical hazards of oxygen therapy (Benditt, 2000) and provides a very interesting discussion on the pros and cons of oxygen for a range of disorders, especially COPD. Again though very little, except fire, is mentioned about the non clinical hazards, with no mention at all about the risk of undetected sudden total loss of supply.

These publications and others (Cooper, 2002; Fisher, 1980) look at very specific issues and seem to completely overlook the serious issue of patients not receiving oxygen when they need it. Gravil et al even go so far as to make a rather disturbing statement in their 'Audit of Oxygen Therapy' in 1997 (Gravil et al., 1997) that "*oxygen therapy should not be routinely administered without knowledge of arterial blood gases and oxygen saturations*." Taking arterial blood samples is a painful procedure and by the time they have the results, the patient could be dead.

2.3.8 *Fire*

West provides a detailed examination of the problem of fire with oxygen enrichment, focusing on long term home therapy (West and Primeau, 1983). They found for example, that below about 40% oxygen concentration, ignition could not be sustained in nasal cannulae. This may be valuable if there is ever a consideration to limit the concentration for home use.

The American Society for Testing and Materials (ASTM) published a collection of papers (Various, 1988) focussing on the problem of materials becoming flammable in oxygen enriched environments. A more recent publication is also available (Hervve Barthelemy et al., 2006).

Hydrocarbons and some metal alloys become explosively flammable in the presence of compressed oxygen, making the use of some common materials such as aluminium and steel unsuitable for use in this context.

Nylon cannot be used with high pressure oxygen and so polytetraflouroethylene (PTFE) is commonly used for sealants and lubricants because it is more compatible with oxygen.

2.3.9 *Current Interest*

There is ongoing interest in oxygen therapy within the academic literature. A recent publication in India by Jindal expresses the need for a review of oxygen therapy, describes how patients should be assessed and how the therapy should be specified (Jindal, 2008). Surprisingly little detail is given of the hazards associated with administering oxygen from a clinical management perspective.

A literature search for the keywords "oxygen" and "elderly" found 80 results, most of which (22) related to surgery and anaesthesia. eleven related to exercise and O_2 consumption, and nine to lung disease. The rest were a mix of

psychiatry, general physiology, metabolic physiology and the effectiveness of long term O_2 therapy.

It is very difficult to find any statistics to assess the level of serious harm caused by oxygen therapy itself. A report sent to the researcher from the National Patient Safety Agency (NPSA) suggests that the number of people harmed each year could be quite a lot higher than most expectations. The sample in the report is too small for any meaningful statistical analysis, but suggests that approximately nine deaths could be caused each year as a result of adverse incidents where a failure of oxygen therapy was the focus of the incident.

2.4 Systems and Complexity

Of considerable importance in this research was the consideration of a ward based therapy as a sub system of ward based healthcare. This in turn is a complex subsystem as depicted in Figure 2-8, one of many in the extremely complex system of healthcare. Although it is not necessary for the reader to be fully versed on the finer points of complexity science, it is useful to have a description of how its fundamentals relate to ward based care.

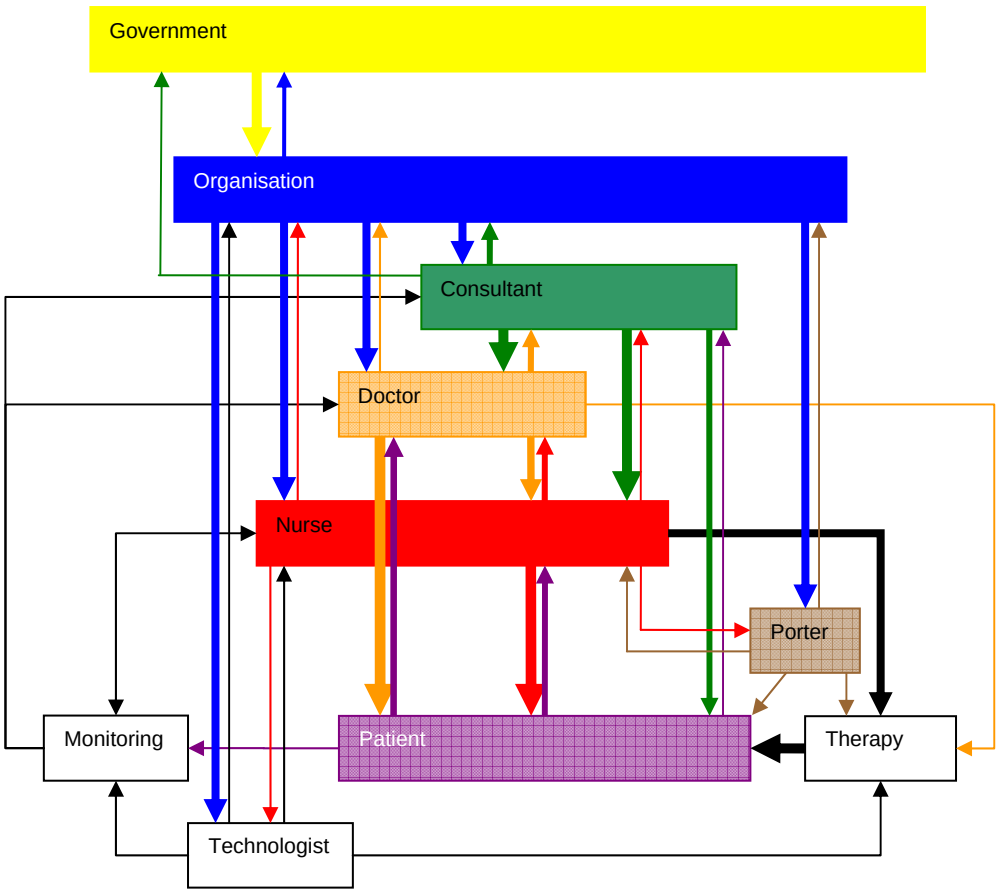

Figure 2-8. The complex system of ward based care. The arrows indicate influence, with the size providing an indication of level.

A complex system is defined by some as one that contains elements from the six principles of complexity assimilated by Webb from work by Stacey in which

eight insights to complex systems are discussed (Webb, 2006; Stacey, 2003) All these are found in ward based care in the following ways:

Self organization and emergence:

This is evident from the autonomy by which senior nurses and especially ward doctors conduct their duties. Both these professions are based on training which is firstly theoretical and then heavily practice based. This allows individuals to find the methods and techniques that work best for them and to formulate their own.

Diversity:

Diversity is manifest in a variety of forms, from the range of professional and practical skills present to the differences in attitudes, personalities and abilities of those delivering the care.

Edge of chaos:

Some of the work done on hospital wards requires dealing with situations that are unprecedented and can at times be extremely dynamic. An incredible amount of creativity is required when dealing with these situations on 'the edge of chaos', and they can lead to highly valuable learning and innovation.

History and time:

History and time play an important role in any experience based endeavour. It is not only the history within the ward that has an effect however, but also that of the health service in general, which percolates down to the front of healthcare.

Time and timing are both crucial for a number of reasons. The more time a patient spends on the ward, the more likely they are to experience an adverse event. "*A patient is at some risk of an incident throughout their hospital stay, and it follows that the longer their stay, the longer the exposure to the risk of an adverse incident.*" (Scobie and Thomson, 2005). The length of the patients stay also affects the cost incurred in their treatment. The bed occupancy needs to be constantly assessed so that hospital management can plan patient movements and admissions; longer stays result in less flexibility.

Unpredictability:

Almost every situation facing clinical professionals is unique. No two patients are the same and often provide their carers with some new challenge. Ward staff also have to deal with the admission of patients outside their own speciality. When bed occupancy is high, a Chinese puzzle ensues in which patients are moved between wards to make room. This leads to cases where surgical patients may end up on medical wards or vice versa. This unpredictability requires a dynamic system, but it needs to be robust as well to give all patients the level of care they require and society and legislation expect.

Patterns:

As unpredictable, dynamic and sometimes chaotic the system is, patterns still emerge. Patients are monitored, fed, medicated, washed and many other things to schedule. Porters and nurses move patients to and from surgery and diagnostic imaging using the same procedure time after time. Some of these

processes are formalised, many are not; emerging from a combination of local leadership and personal preference.

These descriptions leave no doubt about the validity of placing ward based healthcare in the domain of complex adaptive systems (Scobie and Thomson, 2005). To therefore expect such a system to run smoothly without proper hazard management is not logical or professional.

Hazard analysis of a complex system cannot be carried out without clear system representations. To facilitate a robust hazard assessment, the oxygen therapy system had to be defined in a way that helped make sense of the complexity and identified the boundaries within which the analysis was to be undertaken. The system diagram and task analysis flow chart for oxygen therapy (Figure 4-9 and Figure 4-10) were constructed from the author's own experience combined with information gathered during observational research and verified by consultation with senior nurses and consultant anaesthetists.

2.5 Conclusion.

The healthcare environment is a complex and dynamic one with loosely defined methods and procedures that result in a widely variable range of approaches to most therapies and styles of patient and ward management. This makes it a very difficult area for hazard and risk assessment. The safety of patients in any health care environment and the quality of care they receive are of paramount importance. A failure to provide these fundamental needs has devastating effects on the patient, their families (Vincent, 2006a) and the professionals caring for them (Leape, 2006).

There are also financial, economic and efficiency issues to consider. If a patient is killed or severely injured, large compensation settlements can result. Prolonged stays in hospital cost the establishment more (Jones, 2006), especially if additional care is required to deal with incident induced injury.

The patient's extended stay may have detrimental effects on their own finances, which may be passed on to the hospital through litigation. The extended occupation of a bed may also mean that other patients requiring care or treatment have to wait longer than expected, increasing waiting lists and making bed management difficult. Bad press due to publicly perceived sub-standard care can have additional severe detrimental effects on the reputation of individuals, hospitals and the healthcare organization as a whole.

Examining what can go wrong 'at the coal face' of secondary healthcare is a difficult task and has, in general, been poorly addressed. It was to begin to identify a suitable approach for hazard analysis in this context that this research was undertaken. The choice of methods for hazard analysis is staggering (Lyons et al., 2004). Very few have been used in healthcare and those that have were applied to very specific subjects. The seven reviewed in this chapter; FMEA, FTA, ETA, HAZOP, SWIFT, HEART and THERP, were those available to the researcher and they are briefly described. Of these, direct reference to use in healthcare could only be found for FMEA, FTA and ETA. Some indirect references were found relating to HAZOP. A further choice reduction is made in chapter 6, based partly on the results from this review.

Oxygen therapy was described focusing on its administration and management. Some of the major hazards and current research interests were discussed. It is concluded that the variation in process and practice combined with the variation in equipment available for administering oxygen makes for a complex stew of hazards and potential error.

The concept of complexity is discussed in the final section, illustrating how the six principles of complexity apply to ward based care. The methods used to make sense of oxygen therapy before any hazard analyses could be made were also briefly discussed.

Chapter 3 Methodology and Methods

Abstract

This chapter discusses the methodological philosophy and how the 'Pragmatist' epistemological position taken informed the formulation of the research protocol.

The nature of this research necessitated the use of evidence based data to inform the compilation of a comprehensive hazard list. A range of empirical research methods were considered, including; direct observations, interviews, questionnaires, evaluation tests, simulation and document review.

The research design process, including the choice of methods for the empirical studies is discussed. The methods and their application are examined along with the expectations of problems and planned contingencies.

3.1 Methodology

3.1.1 *The Pragmatist Philosophy*

The last two decades have seen a lot of debate on the philosophy of research and the various stances taken in the researchers 'view of the world'. Although claimed mainly by those involved in the Social Sciences, these philosophies have wide ranging relevance. The research in this project is strongly linked to organizational and clinical risk management which are subjects related to the Social Sciences.

The methodology adopted in this research is based around the 'Pragmatist' approach advocated by Colin Robson in his book entitled "Real World Research" (Robson, 2002e), in which he provides a clear explanation and literature review on the subject of approaches to social research.

Positivism, which according to Robson was first described by the 19th century philosopher Auguste Comte, takes a very narrow view of explanation. One of its central tenets is that if an observation can be directly related to a general law, then it has been explained. It also holds the belief that fact born from the application of stringent procedures to quantitative data is the only path to the truth and that science is 'value free'. Positivists believe that reality exists in one form only and that scientists must strive to discover and describe it(Silverman, 2006).

Post positivism is a slightly less entrenched view than the original positivist philosophy. In this view, although there is still only one reality, it cannot be fully known or accurately described. Objective testing of hypotheses is still the central creed, but tempered with the understanding that it is possible for the researchers own values and underlying biases to affect the result of their observations.

Relativism is the other end of the scale, where the belief is that there is no reality other than that created in the human consciousness. In contrast to positivism, there is no more truth in a 'scientific opinion' than any other and

personal values play an important role in describing the world. Purely qualitative methods are used and no attempt is made to discover a common reality.

Constructivism is the slightly more tempered version of relativism in which it is still held that there are many social constructs (hence the name) of reality, but that a construct can be formed which is acceptable and understood by more than one person. Qualitative methods are used which allow the researcher to view a subject from more than one perspective.

The ‘Pragmatist’ approach is located on the continuum between the ‘Post Positivist’ and ‘Constructivist’ approaches. It is part of the ‘Critical Realist’ philosophy and allows the researcher the freedom to make use of the research methods which work best for the task at hand, providing the choice of the best of both methodologies. This endows the research with a rich mix of qualitative and quantitative methods, providing the ‘value laden results from enquiry and the theory laden results from proven fact’ (Robson, 2002e).

Critical realism adopts the ontology of an underlying reality that is complex and perceived differently by individuals in various ‘strata’ such as society, biology, institutional and more. In epistemological terms, it is concerned with the diverse outcomes dependent on the actions of various ‘mechanisms’ applied in a range of contexts (Robson, 2002e).

For example: A candle will light when a *mechanism* for combustion such as a flame is applied (along with fuel and oxygen) in the *action* of touching it to a wick bound in wax when there is a requirement for light (the *context*). A number of *counter mechanisms*, like a strong breeze or the presence of rain, may prevent the candle from being lit. The action may not take place if no mechanism is available, light is not required or is available in a different form.

It is the role of the researcher to observe, either directly or through experimentation, the various outcomes resulting from the range of *actions*, *mechanisms* and *counter mechanisms* within an assortment of *contexts* in order to describe the strata of reality available to them. Although these descriptions can be made, they cannot be used to precisely predict outcome. They can however be used to determine the probability of possible outcomes.

In terms of this research: Structured hazard analysis is being tested as a means to describe the mechanisms which may come into play when certain actions take place in a range of contexts within ward based therapies. The probability of outcomes may be assessed with this knowledge and if the outcome looks more likely to be adverse, counter mechanisms might be engaged to swing the probability closer to a preferred outcome.

Robson explains that research should be carried out with a ‘scientific attitude’ (Robson, 2002a), which entails being:

1. Systematic; taking care to clearly define the scope and reasons for the research. The methods must be well designed with due consideration given to exactly how the research will be conducted and the researcher’s role in it.

2. Sceptical; having an open mind, allowing for ideas to be rejected and providing a platform for scrutiny.
3. Ethical; ensuring that the interests of all parties affected by the research are taken into account and safeguarded.

While these positions are likely true for any philosophical viewpoint, they fit particularly well with the pragmatic stance.

3.2 The Consideration of Empirical Methods

3.2.1 *Observation*

Direct observation has been used before in healthcare research, including nursing based studies (Zeitz 2005; Thomas et al., 2004; Hasson et al., 2005). There are two main categories of observational methods; participant and non-participant (Mulhall, 2003; Carthey, 2003; Blaxter et al., 1996b; Robson, 2002d). These can have a structured approach in which some key elements are watched for and noted according to frequency or other quantitative metrics, while qualitative data like clarity of speech or fluency of action might also be collected.

They might have an unstructured approach in which an observer notes deviations from normal practice or mannerisms or patterns of action. These can be combined in a wide variety of ways to suit the particular research subject. Data collection can be in written form such as structured pro-forma, free text or in diary format, or in electronic form like video or vocal recordings.

In a search for previous observational research designs, no pre-existing flexible qualitative tool could be found in the literature, although some advice on their design was available from Mulhall (Mulhall, 2003) and Robson (Robson, 2002d).

Fitzpatrick et al give an account of their experience in the use of a structured quantitative tool, but do not supply many details about the tool itself (Fitzpatrick et al., 1996). Their review of the literature however, provides useful insights into many of the problems encountered in non-participant observation.

Most observational studies in healthcare research have followed a very structured and controlled method such as those described by Fitzpatrick et al, Undre et al (Undre et al., 2006) and Zietz, (Zeitz 2005), employing quantitative methodologies and relying mainly on statistical analysis.

Much of the research found was concerned with the behavioural aspects of those involved in healthcare. A study by Creedon for example, used a combination of observations and questionnaires to investigate the behaviour of healthcare professionals with relation to hand hygiene (Creedon, 2006).

A few studies have been, in a way, slightly covert with the observer integrating into the group being studied and participating in the activity under scrutiny so that there is a total immersion. An example of this is the doctoral research by Andrews investigating another behavioural issue; that of nurses making a case to clinicians to review patients (Andrews, 2003). As a registered nurse, he was

able to insinuate himself into the research environment and thus become unobtrusive and almost invisible as a researcher.

Those studies that addressed the issue of healthcare provision itself as the focus of the research mostly took the form of audits (Gravil et al., 1997)(Kor and Lim, 2000)(Dodd et al., 2000)(Al-Mobeireek and Abba, 2002).

It was seen that each of the methods of observation and audit had merit in this subject area and so a combination of the two was devised that complimented each other. Structured observations entered into a pro-forma to ensure the collection of some core data was combined with open free text to describe the events observed. The fast-paced, cross-sectional snapshot method often used in audits, facilitated some descriptive statistics and targeted observations.

Observational studies can be very time consuming as they require considerable manual effort at every stage of the process. Making notes while observing events in real time can be very tiring as a great deal of concentration is required. This leads to the need for frequent breaks which also consumes more time.

The notes have to be transcribed, entered into a database or some other analysis device and these transcriptions have to be read and coded and analysed in some way. It is therefore important to clearly define the methods used for this and to set limits of time and/or number of observations to prevent taking too long while still collecting enough relevant data.

It was felt that direct observation was essential for this research as it could provide both an evidence base for the compilation of a hazard list and give the researcher an insight and ‘feel’ for the unquantifiable qualities of ward activities. A flexible approach was taken with a combination of structured audit and free narrative text. The data from these was entered into a custom built database for review and analysis.

The presence of a researcher in the field of study can influence the behaviour of those undertaking the task being observed. This is well documented in the literature (Mulhall, 2003; Robson, 2002e; Fitzpatrick et al., 1996; Grady and Wallston, 1988a). In order to minimise these effects, neither the ward staff nor the patients were told exactly what was being observed, except that it was linked to patient safety. Information sheets (Appendix A1) were available to those who required a more detailed explanation. Notices were also posted on the wards (see Appendix A2) to indicate that observations were being carried out.

3.2.2 *Interviews*

Interviews are commonly used in operational and social research. They too can be structured or unstructured and are sometimes combined with observational methods (Robson, 2002e). A rich depth of information can be gained from them by a skilled practitioner, especially with the use of devices like prompts (suggestions made by the interviewer) and probes (enquiring glances, periods of silence or “hmmmm”). They are especially useful if qualitative analysis is to

be carried out to detect subtle details like body language or to collect useful vignettes.

Interviews suffer many of the same problems as observations, with some added complications like subjects that don't want the interview to end, or are late for appointments. Transcription from recording equipment can also be tedious and error prone.

Due to the fact that ward staff would have to have been removed from their duties for an extended time while being interviewed, there was a risk to the quality of patient care; it was thought very likely that many would choose not to participate for this reason. Interviews were therefore deemed inappropriate.

3.2.3 *Questionnaires*

Some researchers seem to consider questionnaires to be a purely quantitative method (Silverman, 2006) and others appear to see them only as one of the tools for the collection of survey data (Robson, 2002e). If however, they are viewed as a simplified extension of an interviewer, they can be used as an alternative to interviews when access to interviewees is an issue or there is a large sample population.

Some time is still required from the participants, but this can be reduced and the responder can complete it according to their own schedule. A questionnaire can however cause a loss of depth to the data as body language, tone and side remarks can not be recorded (Robson, 2002e).

A great deal of thought and design is required in order for questionnaires to be effective (Blaxter et al., 1996a) and although validated designs are available for purchase or distribution from specialist survey agencies (e.g. MORI (Ipsos MORI, 2008)), these are mostly marketing or politically focussed.

Transcription of interviews is extremely time-consuming whereas much of a questionnaire may not require this. Instead of the time being consumed talking to people as in interviews, there is often a long wait for the required number of responses to be returned, although this time can be constructively used. Response rates to questionnaires can be extremely low, possibly invalidating a study.

Since interviews were not feasible, it was decided that a questionnaire would be the most effective alternative in order to benefit from the valuable tacit knowledge and experience of professionals engaged in ward based care.

Questionnaires are common in healthcare research and have been used in many topic areas including domiciliary oxygen therapy (Neri et al., 2006/5). Those studies concerned with hazards or risk have tended to focus on the attitudes of the respondents (Kobbeltvedt and Brun, 2004), or their knowledge and competence within legislation or guidelines (Askarian et al., 2004; Ayranci and Kosgeroglu, 2004).

Few publications give details on the questionnaire design process and most use pre-designed, verified questionnaires (Neri et al., 2006/5; Itoh et al., 2006), while some quote the standards on which they are based (Leliopoulou et al., 1999). No suitable verified questionnaire was found for this research, resulting

in the need for one to be custom designed. In order to allow frank and open answers, questionnaire respondents needed to be completely anonymous.

The methods of distribution and return or collection had to be carefully considered to provide the best likelihood of a high return rate. In this case, the researcher distributed them by hand to ward managers and they were returned via the internal mail systems of each hospital.

3.2.4 *Task Evaluation*

Task evaluations are normally conducted for the assessment of an operator's ability to complete a given task to a required standard (Breakwell and Millward, 1995)(Kirwan and Ainsworth, 1992). Role-play within a defined simulated event is a common format (Garnerin et al., 2007). Evacuation tests and cockpit simulations are used in the aviation industry, while the emergency services use this technique to conduct evaluations of their ability to cope with large scale crises.

Task evaluation tests have to be very well designed and a validation process should be undertaken to ensure their usefulness, which in combination causes an extended design stage. They are also time-consuming in their execution with similar issues to interviews, questionnaires and observations coming into play in their analysis.

These would require the participants to volunteer their own time or for the institution to allow them the time to take part. It was thought that this was unlikely to be possible and task evaluation was therefore rejected.

3.2.5 *Computer Simulation*

Computer simulation is comparable to task evaluation in that it is an artificial construct of an event or situation, but uses a computer model rather than real people and spaces. Detailed descriptive data of all aspects of the subject under review has to be assimilated and embedded within the model in order to define the behaviour of each element.

This, however, requires that much of the knowledge that this research was expected to produce should already be known. Computer simulation was considered inappropriate for this stage of this research, but might be useful as an optimization method in future work.

3.2.6 *Document Review*

Document review requires the use of coding methods to allow a document to be read and markers attached to the text. This enables a wide range of qualitative and quantitative analysis. Specialist software is available for this method (Robson, 2002e; Silverman, 2006), or bespoke software programs are sometimes designed. Documents may be transcripts of interviews, historical texts, or even novels.

They work best with multiple readers and a logical design to ensure their validity and reliability; much time can be wasted through poor design. Reading and categorizing or coding text is also very tedious and requires high levels of

concentration. Over-taxing readers can cause them to lose interest in the task and so become bored and thus errors can be introduced.

In the context of this research, Local incident reports, patient complaints and clinical notes were all considered as potential sources. Also considered were national incident reports filed by clinical staff into a national electronic database held by the National Patient Safety Agency (NPSA). It was resolved that the best option was that of local and national incident reports and access to these potentially sensitive documents was negotiated with each trust, while that of national data was made with the NPSA.

It was decided that this was a useful way of testing the hazard list and amending it if required. A method was devised to add to the risk analysis conducted in the observational study.

3.3 Research Design

3.3.1 *Requirement*

The eventual result from the empirical research and that of each of the hazard analysis methods had to be comparable. It was decided that the most logical common form was that of a hazard list and an associated risk analysis. A selection of a number of empirical methods had to be made to facilitate the generation of the hazard list. These had to offer differing perspectives in order to compliment each other and one needed to be used for the final testing and validation of the hazard list.

A validation process was required to provide the most reliable hazard list possible. It was felt that the best way to do this was to apply the hazard list to some recorded data, such as; local incident reports, patient notes, patient complaints or national incident reports and use the results and the opinions of a number of readers to assess validity through discussion and by applying a statistical measurement of reliability. Incident reports were felt to be the most relevant to this research and were more likely than the other sources to identify hazards.

As reliable probabilistic data is almost impossible to generate with this sort of research, some other metric needed to be found as the basis for a risk analysis. Various options were considered as denominator data, including; bed days, therapy hours, patient admissions and patients per ward. These were felt to be either unreliable due to sampling difficulties or not specific enough.

A measure of relevance based on the number of times a particular hazard was recorded and the reliability of the count was thought to be of most use in this context. Once a valid hazard list was achieved, the final step was to apply the list to a large sample of data and use the statistical computation of Krippendorff's Alpha ($K\alpha$) (Krippendorff, 2003a) for reliability combined with a weighted score of recorded harm as the basis for a risk analysis.

3.4 Research Design Considerations

3.4.1 *Ethics*

The ethical issues in healthcare research have to be carefully considered. Patient confidentiality and privacy are high on the list of concerns, especially when observations are made on hospital wards. Hospital patients can be very vulnerable, especially children or those with special needs. Ward staff also need assurance of confidentiality in both observational studies and questionnaires or interviews (Grady and Wallston, 1988b).

Care was taken in the design of the studies in this research to avoid adverse impact on these issues. In hospital settings, informed consent is not always possible. This was the case in this research as many patients would have been unable to provide such consent due to their state of consciousness or simply because they would not have been able to give due consideration (Grady and Wallston, 1988b).

No information specific to the patient or any member of staff was collected or inspected. During observations, patient privacy was given high priority and great care was taken to avoid making patients or staff members feel uncomfortable.

It was important that ward staff were at ease about the intention of the researcher and the research, especially in clinical areas. The patients also had to be comfortable with the presence of the researcher, especially during clinical or nursing procedures of a personal nature. If participating in interviews or questionnaires, they had to feel secure about answering any questions.

At no time was patient or staff safety to be compromised as a result of the research. Every action had to be carefully assessed. Getting in the way of ward staff, taking up too much of their time or causing them to be distracted were all carefully avoided.

Children and vulnerable adults are just as likely as anyone else to need ward based care. It was thus inevitable that these patients would in some way be included in this research (Grady and Wallston, 1988b; Robson, 2002b). Special attention was paid to ensure that they were not frightened, confused or misled about the presence, role or purpose of the researcher. Prisoners would have been treated as any other patient if on open wards, but excluded if in a private room; none were however part of this research.

The need and value of the research has also to be justified when making ethics approval applications. Research for purely commercial reasons or to gain some leverage or influence would be hard to defend {{}}(NPSA, 2008a). In the context of this type of research, there should be some demonstrable advantage for patient care or treatment, whether directly in the form of improved therapeutic or diagnostic methods or indirectly through better quality of patient management or general operational procedures.

This research directly affects patient safety through the hazard assessment of oxygen therapy, thus providing valuable information for the improvement of

hazard barriers to prevent adverse events. It also indirectly affects patient safety generally by providing an evaluation of assessment methods through a comparison with results from empirical research.

Ethics considerations for the storage of data and security arrangements for its protection were also made. These were managed by the careful use of the established I.T. infrastructures of the institutions involved.

The likelihood of completion of the research is extremely important when proposals are being considered by ethics committees. It is unacceptable for research to be conducted that incurs costs and intrudes into the lives of people and then produces no result. Likelihood of completion, and quality of research design and analysis were monitored and supervised by senior staff at Cranfield University.

Ethics approval for this research was awarded in the first instance by favourable opinion from the Bedfordshire Local Research Ethics Committee on the 11th May 2006. This gave approval for a multi-site project without the need for site specific assessment and covered the observational studies, the questionnaire and the review of local incident reports at the participating hospitals. A number of possible hazard analysis methods were listed in the application, but none had been finally decided on at that stage.

A notice of substantial amendment was submitted to the National Research Ethics Service, now under the management of the NPSA, on the 25th of October 2007. The amendment was given a favourable opinion on the 9th of November 2007. It included the review of national incident reports and held more detail about the hazard analysis trials, especially the HAZOP as this was expected to be the most resource intensive method to be evaluated.

3.4.2 *Access to the 'Field'*

Research of this nature requires a certain amount of negotiation with the 'gatekeepers' at the relevant institutions (Mulhall, 2003). Not only do they need to assess the ethical content of the projects presented to them, but also the effects it may have on their patients, the staff and the institution in terms of resource management, publicity and legal position.

As this research was in a sense 'commissioned' by Bedford Hospital NHS Trust, many of the problems usually encountered with access were eliminated at that hospital. It was however, for governance reasons, still necessary to submit a proposal detailing the studies based within the hospital and to apply for an honorary contract.

The first major problem to overcome was getting the co-operation of the senior staff in charge of the wards to allow the observational study to take place. This entailed lengthy introductions by a senior member of hospital staff, which in itself generated a small amount of suspicion. Some of the ward staff were concerned that this was a management based project with the aim of "squeezing more blood from the workers" as Robson puts it (Robson, 2002c).

Staff availability played an important role in deciding on how the research was to proceed. The amount of time any method took for participants had to be judged, as their absence from the wards might have jeopardised patient care.

To avoid the effects the knowledge of the research subject might have on staff behaviour (Robson, 2002e), it was necessary to limit the detail supplied to them about what was being observed. Care had to be taken not to withhold too much, as research codes of practice and ethics requires that the researcher be as open as possible (Grady and Wallston, 1988b; MRC, 2008). The ward staff were also apprehensive about the disruption the presence of a researcher might have to the normal operation of the unit. There was therefore, a balance to be struck, not only to limit contamination of the observations while maintaining rapport with the staff, but also ensuring ethical practice.

One particular issue never resolved was that of access for night shift observations. It meant that night observations were not made as getting in contact with the staff involved was difficult and some of them were uncomfortable with the presence of a researcher on the night shift.

The researcher's previous employment as a Senior Technologist at Stoke Mandeville Hospital gave him some advantage in that he was known to many of the ward and management staff. A very similar procedure for research registration and approval to that at Bedford Hospital was followed, with the exception that introductions of the same type were not required. A lot of time was still spent negotiating access, and similar problems were encountered regarding the night shift.

Adequate access to both sites was agreed and maintained throughout the project and no irresolvable problems (besides the night shift observations) were encountered in any of the studies. Active interest from the senior anaesthetists at Bedford Hospital resulted in their involvement in the incident report review study. This made it possible to extend this study beyond the local reports originally intended to involve a large number of nationally reported incidents.

A data sharing agreement was made with the National Patient Safety Agency for access to the national incident reports held by them. The main point of the agreement was to maintain patient confidentiality and ensure that the anonymity of those making incident reports was not breeched.

The security of all involved had to be considered. Valuable items required for the research may have been at risk to theft in some more public areas and so required safe storage or remained in the possession of the researcher at all times. Arrangements were made to give the researcher the right to be in the clinical areas and all concerned needed to be notified. Some means of governance and protection needed to be afforded to the researcher. Many of these issues were resolved by each trust awarding an honorary contract to the researcher. This provided the required security protection and governance, as well as access to clinical areas and local data. Access to wards or other clinical areas still required the negotiation of permission with ward managers and patients and staff had to be notified that research was being conducted on the ward.

3.4.3 *Time and effort*

Designing the research, data acquisition, analysis and writing all consumed project time and required considerable effort. This had to be considered when choosing methods and setting boundaries.

3.4.4 *Analysis*

Any chosen methods had to produce results that could be analysed using mainly qualitative techniques such as risk analysis and content analysis. Some descriptive statistics could be used to augment and supplement the analysis, but as the data was unlikely to have high levels of accuracy or precision, it was seen as pointless to try and rely on quantitative methods.

3.5 Expected Problems

3.5.1 *Researcher Bias*

As this is primarily a single researcher project, the possibility for the researcher to inadvertently affect the result is strong, especially with the observational study. It was anticipated that the questionnaire and the document review ought to minimise the effects of any such bias.

Another bias issue is that of ‘contamination’ of the results of the hazard analyses through prior knowledge gained from previous analyses, e.g. the experience from a FMEA affecting the outcome of a HAZOP.

To try and minimise this, the empirical research was conducted before any hazard analyses were attempted. This was intended to impress a good insight into oxygen therapy upon the researcher which reduced the learning provided by the act of conducting the hazard analyses.

The drawback to this was that there was now a chance for the researcher to subconsciously ‘fit’ the results of the hazard analyses around the results of the empirical research. This was thought to be less of a problem as it would at least be similar for all three hazard analysis methods. The hazard identification processes for all three hazard analysis methods would be partly produced through discussion with others and so would be further minimized.

3.5.2 *Access*

Problems associated with access to busy staff and clinical areas was anticipated and dealt with through tactful and sensitive negotiation and involvement with key personnel.

3.5.3 *Assessment of patient safety risk*

Obtaining or producing probabilistic information for risk assessments in this context is almost impossible. Many observed events were also not likely to be taken through to their eventual consequence.

For the observational study, the risk assessments were made once all the observations were complete so that some informed estimate could be made of the likelihood of an event. The outcomes were also in the most part judgments

on whether there was an increased likelihood of failure, aversion of an incident or an improvement to the therapy.

During the risk analysis within the document review of incident reports, instead of probability, a measure of relevance was needed somewhat similar to those used by search engines for the ranking of results. These use a variety of methods, all kept well guarded, that make use of the number of times an item is found and the choices made by previous searches of a similar nature.

An algorithm was developed for this research making use of the number of times a taxonomy element was selected and the level of agreement on this by the researchers reading the incident reports.

More details are given on these in later chapters.

3.6 Conclusion

This chapter discussed the philosophical side of the methodology explaining how the ‘Pragmatist’ position was adopted for this research.

The various empirical methods available were considered and their selection for use in this research was discussed. It was decided that observations in the ward environment were crucial and that a practical solution to learning from the experience of healthcare professionals was to make use of a questionnaire. Document review was used as a means of validating the hazard list resulting from the observations and questionnaire, with incident reports used as the source for this review.

The early expectations of results were briefly discussed as were solutions to the initially anticipated problems. The issues surrounding researcher bias, ethics, access to the field and the difficulties of constructing a risk assessment were examined in some detail.

Chapter 4 Observing Events and Asking the Experts

Abstract

This chapter describes two empirical studies linked by the common aims of:

1. Producing a hazard list to be used for comparison with the results of each of the hazard analysis methods
2. Construction of a common frame of reference for the hazard analyses.

Observations followed by a questionnaire, forming two points of the triangle describing the 'Combined Evaluation Data' in Figure 1-2 (section 1.2), were undertaken at two NHS Trust hospitals.

The observations identified 684 discreet events, 43 of which (6%) were assessed as adverse. The results of an audit forming part of the observational study were used to provide a denominator for these results and suggested that if 6% of therapy episodes resulted in an adverse event, as many as 81,454 patients may experience an oxygen therapy related incident per year.

The questionnaire identified 54 hazard themes. Patient compliance, concern over the management of patients with Chronic Obstructive Pulmonary Disease (COPD) and the issue of empty cylinders were some of the major themes, along with prescriptions either not made out or incorrectly written, dosage errors, staff training and inadequate guidelines.

Over 600 combined hazard themes were distilled down to 119 distinct hazards. These are included in the hazard list in Appendix C1. A system diagram with three sub-systems and twelve elements was constructed (Figure 4-9) as was a simplified process map (Figure 4-10).

4.1 Introduction

Direct, non-participant observations with a mainly qualitative focus were made at Bedford and Stoke Mandeville Hospitals from the 8th of June to the 7th of December 2006. These were followed by a questionnaire study at each site beginning from the 20th of October 2006 until the 19th of March 2007.

The primary purpose of this part of the research was to observe events during the administration of ward based oxygen therapy and make use of the experiential knowledge of professionals in the field in order to identify and define possible hazards. A secondary function was to allow the researcher to gain familiarity with the context of this therapy, since hazards cannot be defined or analysed without clear contextual association. This information was then used to construct a common frame of reference, which later in the research became the basis for the formal hazard analyses. This was therefore not only an attempt to look for hazards or errors, but also a more holistic non participant immersion in order to get "a feel" for the process and its setting.

As thorough as any observational study might be, it is highly unlikely that every type of event will be observed. The questionnaire study was therefore

conducted as an adjunct to the observations, with the intention of capturing some of the tacit knowledge possessed by professionals who work with oxygen therapy daily. In order that the questionnaire could not interfere with the observations by alerting the clinical staff to the subject under scrutiny, it was distributed at each of the two sites only once the observations there were completed.

The questions underlying this combined study were:

1. What hazards related to oxygen therapy can be identified and defined in terms of hazardous elements, initiating mechanisms and threats?
2. What common frame of reference for the formal hazard analyses can be constructed from the knowledge gained on the context of ward based oxygen therapy?

The common aims were:

1. To construct a hazard list using the combined data from both studies.
2. To construct a common frame of reference for later use in the formal hazard analyses by:
    a. Identifying all the components of the oxygen therapy system.
    b. Gaining familiarity with the practical issues faced by those involved in the administration of oxygen therapy on wards.

The objectives of the observational research were:

1. To identify and define hazards by:
    a. Observing events surrounding the administration and monitoring of oxygen therapy including the interactions between staff, patients, visitors and the oxygen therapy equipment.
    b. Assessing the threat posed by the identified hazards through the consideration of possible outcomes of observed events.
2. To obtain an estimate of the denominators for this research by:
    a. Identifying methods commonly used on hospital wards for the delivery of oxygen therapy and how these are set up, monitored and managed.
    b. Calculating an approximation of the number of patients receiving oxygen therapy daily and the frequency of methods of administration.

The questionnaire had the following objectives:

1. To identify hazards experienced by practitioners.
2. To estimate how often practitioners experience cases of harm to patients due to failures of oxygen therapy.

3. To rank some previously identified hazards by proportional frequency.
4. To gauge the attitudes and perceptions of practitioners with regard to patient safety with oxygen therapy.

4.2 The Observational Research

4.2.1 *Observation of Events*

Detailed observations were made over a six month period, first at Bedford Hospital and then at Stoke Mandeville. These were recorded by hand in both tabular and narrative formats. Event descriptions were written in a diary format before being converted to discrete events, while structured audit data were entered into an observation chart (see Figure 4-2). Both were then entered into a database.

Studies were conducted in a variety of wards and departments in the two hospitals in order to ensure as much variation as possible. The researcher moved about within each ward or floor, noting the way that the therapy was set up for each subject and how it was managed. Some preliminary, less structured observations were made very early in the research to get an idea of what should be included in pre-defined lists and to make any amendments to the observation chart or database design.

Information on ward layout was collected and notes were made of some general activities which together shaped the environment that formed part of the context for the therapy. As much detail as possible about the observed subject and the surrounding environment was collected. Notes were made of peripheral tasks such as those related to other therapies or activities on the ward. Where possible, annotations were included about how these might affect oxygen therapy or be affected by it. Ease of movement and access to patients and equipment were observed as were difficulties for the staff to see patients and monitor them. Some simple trace studies were also performed by following patients during transfers from one hospital area to another, looking for any specific environmental or task related hazards.

An effective general strategy for each study was found to be as follows:

1. An audit round of each ward within a defined area of the hospital was conducted. This was an adaptation made towards the end of the period at Bedford Hospital and continued at Stoke Mandeville.
2. A ward or floor was chosen for detailed observations.
3. Introductions were made to the staff and permission gained from those in charge for access to the ward where observations were to be performed.
4. Where required, a diagram of the ward layout was drawn. This helped to keep track of where subjects were and aided in assessing the layout for hazards.
5. Details of the therapy set-ups and any observed hazards or problems were noted.

6. Three to five minute watches were made on an area, taking up a different position each time when possible. This period was extended when an event was in progress or a trace study was made. It was important not to appear to be staring at a patient to prevent unnecessary uneasiness.
7. Awareness of the following general ward activities was maintained:
    a. General nursing tasks
    b. Doctors rounds
    c. Drug rounds
    d. Catering, cleaning and other ‘hotel’ services
    e. Visitors’ movements and actions
    f. Shift changes
    g. Other therapies
    h. Actions of other patients
    i. Estates and operational services activities

The research was structured as a collection of studies at each research site as depicted in Figure 4-1. A site was defined as the collection of buildings forming a hospital. A study was defined as a group of observations at a particular site within a single visit. A location was defined as the department or ward where the research was being conducted. An observation was a number of events relating to the same subject during any study. A subject was the combination of a patient receiving oxygen therapy and the bed-space occupied by them. An event was defined as any instance where an action or task was carried out on or near a subject.

There was some curiosity from both staff and patients regarding the presence of the researcher and a mixture of questions and comments were received. Most patients and members of ward staff were very pleased that there was some consideration of patient safety taking place. No hostility was experienced other than one instance where a ward sister was reluctant to allow the researcher access to the ward until completion of a rather lengthy exercise in verifying that permission had been given for site-wide access.

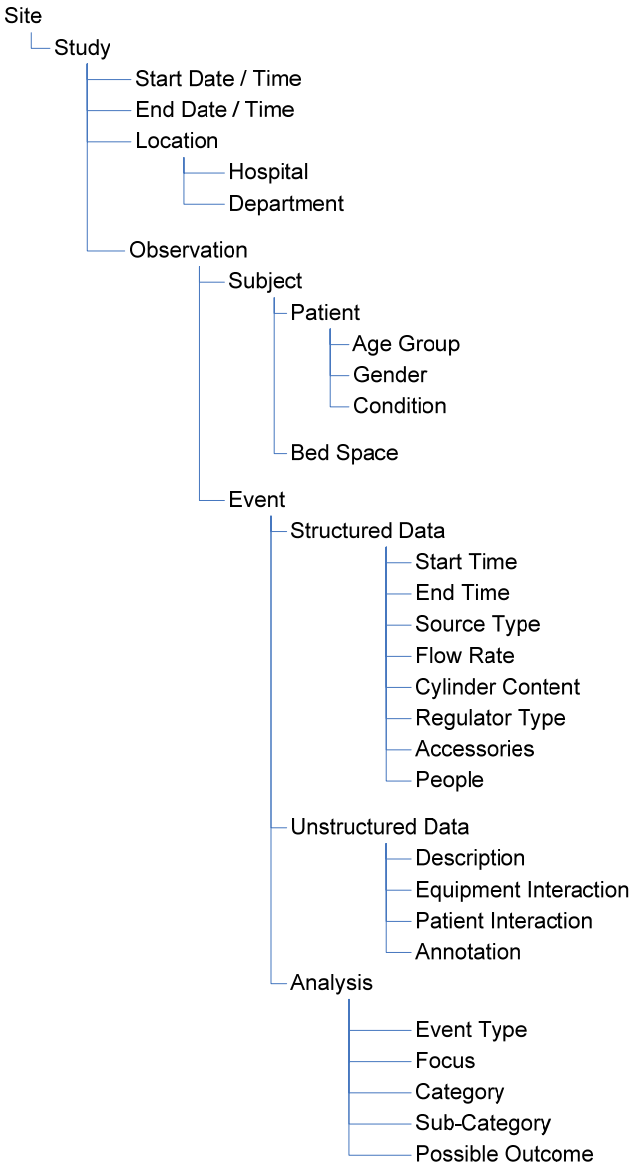

Figure 4-1. Observational Research Structure

4.2.2 *Audits*

Audits were used both during and before event observations to collect information about the number of patients on oxygen and the methods of administration. The details of the equipment and some basic information on the subjects were collected using the structured observation chart of Figure 4-2. This allowed an estimate of the daily frequencies of these to be calculated. Types of events and interactions were also noted when observed.

When performed before full observations commenced, they also helped in the identification of suitable subjects and in some cases to observe specific hazards. This information was used immediately to identify areas of the hospital where the most subjects for observation were, or to locate subjects with specific

characteristics; like those that might soon be transferred or those using cylinders.

No.	Time	Ward	Subject	Flow	Accessories	Source	Details

Figure 4-2. The table headings used for audits and structured observations.

The tabular and discrete event data were both entered into a database and linked as part of the same observation where appropriate. The data were analysed by open categorization and consequence analysis and the results used to produce some descriptive statistics and assist in the formulation of a hazard analysis.

Some general descriptive observations made separately to those linked to events remained as diary entries only and were not entered into the database. These were mainly annotations and comments which provided a useful source of qualitative data and contextual linkage.

4.2.3 *The Database*

A bespoke database system was constructed for the collection and analysis of audit and event data. The structure of the tables forming the core data and their relationships is shown in Figure 4-3.

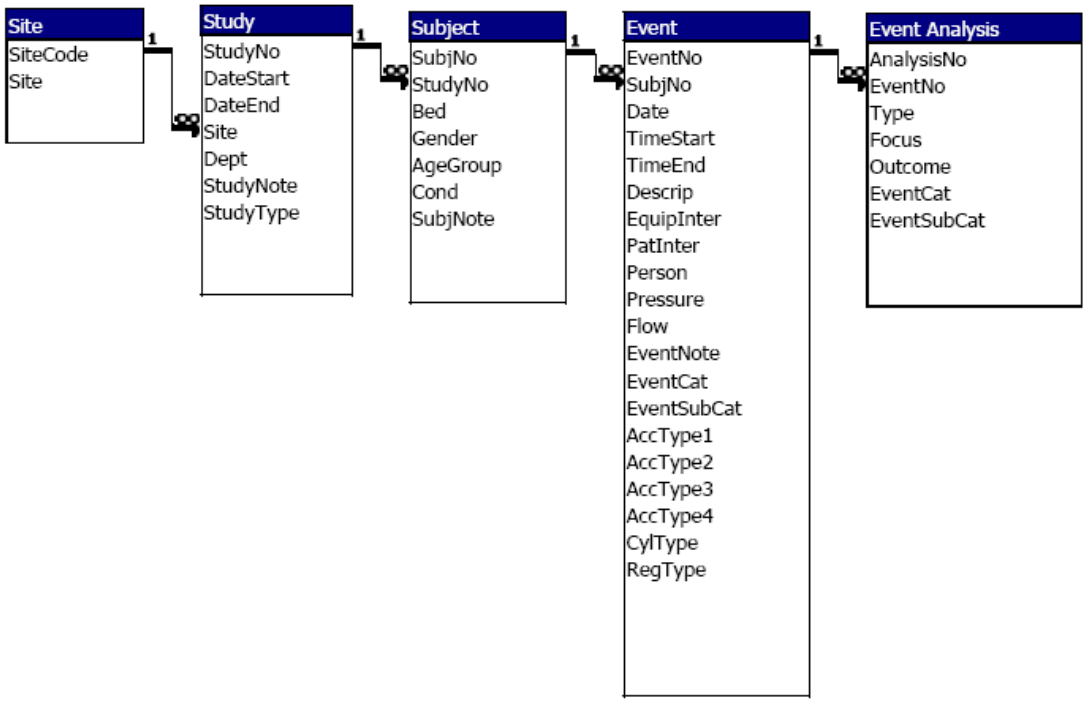

Figure 4-3. Core database tables and relationships

The data was analysed by:

- Extracting events from the diary and the observation chart and entering them into the database.
- Identifying hazard themes through open categorization of events to produce a list of hazard categories refined using a process of rationalization.
- Estimation of event risk by selection of possible outcomes from a pre-defined list.
- Using a combination of hazard categories, outcomes and diary entries to produce a hazard list and basic analysis.
- Using descriptive statistical analysis to identify:
  - the most common methods of administration
  - the most common events and interactions

4.2.4 *Event Extraction*

Events were identified from the diary as any discrete occurrence with an apparent or possible local effect. The identification was not limited to adverse events, but included those that were neutral or favourable in order to aid in observing safe or correct occurrences.

4.2.5 *Categorization*

The categorization emerged from the data along the lines of the grounded theory method used in social research (Robson, 2002e; Silverman, 2006). Each event had any number of categories of hazard attached. These were not taken from a pre-defined list, but merely short descriptions of the hazardous elements within the event.

Once an initial list of categories was constructed by an analysis of the complete set of events, it was rationalized by giving the same label to those categories that were essentially the same. The result of this rationalization combined with the outcomes assessments were the basis for a preliminary hazard list which was further developed from the results of the questionnaire. The later review of incident reports was used to validate and amend this basic hazard analysis.

4.2.6 *Outcomes Assessments*

The pre-defined list of possible outcomes in Table 4-1 was devised by taking a systems analysis approach. Not all events had a negative outcome; some had no effect (Neutral) while others prevented an otherwise negative outcome (Aversion) or made a failure less likely (Decreased Probability of Failure).

Table 4-1 Possible outcomes ranked in order of 1= most negative, 13= most positive.

Rank	Consequence	Definition
1	Death	Patient dies as a result of the event
2	Serious Injury/Severe Worsening	Patient is permanently harmed or life is threatened
3	Minor Injury/Slight Worsening	Harm is not permanent or life threatening
4	Discomfort	No actual harm
5	Delay	An action or result is delayed
6	Next Event Trigger	This event causes a negative outcome in a future event
7	Increased Probability of Failure	Postulated worsening of system reliability
8	Near Miss	Negative outcome narrowly escaped
9	Undetermined	Outcome could not be defined
10	Neutral	Event had no effect on the system
11	Decreased Probability of Failure	Postulated improvement in system reliability
12	Improvement	Outcome reduced to neutral by planned action
13	Aversion	Negative outcome avoided by planned action

4.2.7 *Categorization Results*

Twenty five observational studies were conducted across both sites (eighteen at Bedford and seven at Stoke Mandeville), during which 499 observations were made.

There were 102 categories of events identified, resulting in 223 unique category/subcategory pairs. The categories with the highest frequency are shown in Table 4-2. Unsurprisingly, given that mainly task related events were observed, most of these have a strong human factors bias. Related factors such as environment and staff levels are likely to have also played a role in the events surrounding these categories. A table of all 223 category/subcategory pairs is given in Appendix A3, Table Appendix A.3-1.

Table 4-2. Category Frequencies

Category	Count	% of Events
Nursing Tasks	106	15%
Nurse Actions	102	15%
Patient Actions	94	14%
Accessory Displacement	74	11%
Therapy Administration/Monitoring	71	10%
Therapy Adjustment	69	10%
Patient Monitoring	55	8%
Patient Transfer	47	7%
Other Therapy	47	7%
Supply Change	46	7%

A total of 684 events were analysed; 151 had favourable outcomes, 297 were neutral or undetermined and 236 were less favourable with 43 of the latter seen to have been adverse. Most outcomes, as shown in Table 4-3, pointed to an increased probability of failure (193, 25.63%). Of these, the most common type of event was setup issues (75, 9.96%), with accessory issues (22, 2.92%) being

the most frequent within these. The complete outcomes assessment is shown in Appendix A3, Table Appendix A.3-2.

Table 4-3. Outcomes and Frequencies

Consequence	Count	Unfavourable	Neutral/Undetermined	Favourable
Increased Probability of Failure	193	193		
Neutral	176		176	
Undetermined	121		121	
Decreased Probability of Failure	88			88
Improvement	50			50
Discomfort	22	22		
Aversion	13			13
Near Miss	9	9		
Next Event Trigger	8	8		
Minor Injury/Slight Worsening	3	3		
Delay	1	1		
Serious Injury/Severe Worsening	0			
Death	0			
Totals	684	236	297	151

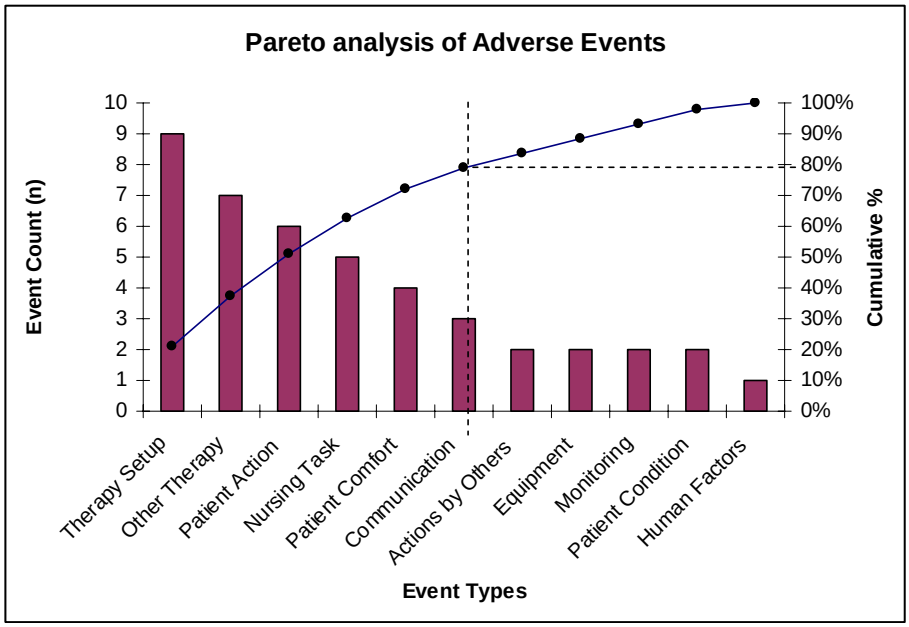

Figure 4-4. Pareto Analysis of 43 adverse events.

A Pareto analysis of the 43 adverse events is presented in Figure 4-4. This indicates that events related to the setup of the therapy, those involving actions focussed on other therapies, patient's actions, general nursing tasks, patient comfort and communication make up approximately 80% of the adverse outcomes.

General observations that could not be classified as events pointed to:

- Poor management of cylinders: Very few wards had designated storage areas and those that did made poor use of them. Full and partly used cylinders were stored together and even some empty

ones were found among these. Ward staff were sometimes unsure whether replacement cylinders had been ordered. When full cylinders were delivered, these were often left in the same position where the empty ones had been and no-one was notified about their arrival.

- Procedural and communication issues during patient transfers and handovers: The use of checklists either before or after transfers was not observed. The ward staff were sometimes unaware that a patient was due to arrive or be collected by porters. Details about the patient were often hastily called out to seemingly no-one in particular and there was one instance where a patient's written notes were mislaid.

Many events were benign or undetermined in outcome and these helped to form an overall idea of the system of oxygen therapy and its contextual basis.

Using the categorical data in combination with the outcomes, a hazardous element list was compiled (Appendix A3, Table Appendix A.3-3).

4.2.8 *Audit Results*

Audits of therapy methods, accessories used and an estimate of the number of patients on oxygen therapy yielded the following results:

Standard Hudson masks were the most common accessory observed with 236 (47.3% of events). Nasal cannulae were the next most common with 113 (22.6%). Together these account for approximately 70% of the patient connected accessories in observed events. The full range of accessories and the number of times they were observed can be seen in Table 4-4 along with the corresponding percentage of events. (These add up to more than 100% because more than one accessory was often observed per event.)

Table 4-4. Accessory Count

Accessory Description	Count	% of Events
Hudson mask	236	47.3%
Nasal Cannula (specs)	113	22.6%
Humidifier	60	12.0%
Large Bore Tubing	57	11.4%
Non Re-breathing Mask	49	9.8%
Laryngeal mask	26	5.2%
Head box	26	5.2%
24% Venturi (Blue)	16	3.2%
Venturi Mask	11	2.2%
Nebulizer	10	2.0%
Resuscitation Bag	8	1.6%
Paediatric Mask	8	1.6%
Tracheostomy mask	7	1.4%
28% Venturi (White)	6	1.2%
Tracheostomy T-piece	5	1.0%
Ventilator Assisted	2	0.4%
40% Venturi (Red)	2	0.4%
35% Venturi (Yellow)	1	0.2%
Mouth Piece	1	0.2%
Resuscitation Circuit	1	0.2%

Fifty five (23.2%) of the 236 events involving face masks were at flow rates lower than five Litres per Minute even though advice (Cooper, 2004; Kallstrom 2002) and guidelines (Fulmer et al., 1984), including those in place at Bedford Hospital state that they should not be used at these low flow rates. This may be indicative of incorrect or out of date guidelines, or a disregard or lack of awareness of them. Of the remaining 181 events, 156 were at flow rates of five Litres per Minute and over. All of these should, according to advice (Fulmer et al., 1984; Bateman and Leach, 1998) and local guidelines, have been humidified, but only thirty were; meaning that almost 81% of the therapies that should have been humidified were not.

An estimate of the daily percentage of admitted patients on oxygen was made according to Table 4-5. The average number of beds audited, together with the average number of patients seen to be on oxygen, indicates approximately eight percent of admitted patients receiving oxygen therapy per day.

Table 4-5. Average Daily Percentage of patients on Oxygen.

Audited beds at Bedford Hospital	235
Audited beds at Stoke Mandeville Hospital	230
Average total beds per audit	232.5
Average no of patients on oxygen per audit day	18.25
Average % patients on oxygen per day	7.85%

This concurs with two published audits (Gravil et al., 1997; Akbar and Campbell, 2006) and when combined with others (Small et al., 1992; Attia et al., 2004; Akbar and Campbell, 2006) as in Table 4-6, shows that an average of 22.4% of admitted patients receive oxygen. The Australian study was of short duration

and only included medical wards, which may account for the high percentage of patients on oxygen.

Akbar and Campbell performed two separate audits in their study, hence they have two entries in the table. These audits were not designed to collect this particular statistic and excluded many patients who might have been on oxygen therapy but were missing from their beds, having other respiratory treatment, were eating, had visitors or were being seen by their doctor. Patients who had been included in the first audit were also excluded from the second.

Small et al also based their study only in medical wards and included patients where oxygen therapy equipment was present even if it was not in use. These together possibly account for the high percentage of cases.

The Gravil et al and Durand studies are similar in methodology in that they were 'snapshot audits' which gathered data on single days separated by an intervening period. The Gravil study was however of shorter duration, covering three observation days separated by at least a week. The Durand study also did not cover all the wards on every occasion, as the main aim of the study was to observe process rather than perform an audit.

As these studies vary in methodology and purpose, it is felt likely that the averaged result is a valid, but cautious reflection of the generalized proportion of admitted patients that receive oxygen therapy.

Table 4-6. Average Percentage of Patients on Oxygen.

Study	% Patients on oxygen
Attia (Australia)	65.33
Akbar (UK)	16.36
Akbar (UK)	10.73
Small (USA)	29.09
Gravil (UK)	5.00
Durand (UK, This study)	7.85
Average percentage	22.39

The above average was assumed to be valid over a year and was applied to admission episodes reported in national statistics in the UK for 2006/7 (Health and Social Care Information Centre). It was estimated that 22.4% of the 12,976,273 reported admissions approximates to a staggering 2.9 million patients receiving oxygen per year in the UK alone. Even taking a conservative approach using just the UK based studies which average to about 10%, amounts to approximately 1.3 million oxygen therapy episodes.

Disregarding the 193 observed incidents shown in Table 4-3 with outcomes believed to have produced an increased probability of failure, 43 (6%) of the total 684 observed events were seen to have been adverse, suggesting that as many as 82,000 patients may experience an oxygen therapy related incident per year.

4.3 The Questionnaire

4.3.1 *Design and Deployment*

In designing the questionnaire, the following points were considered:

1. The respondents had to be engaged by the introduction.
2. The research aims had to be addressed.
3. The questionnaire had to be as short and concise as possible.
4. The deployment method had to be as targeted as possible.
5. The respondents had to remain anonymous.
6. The questionnaire could not be allowed to inform the clinical staff of the precise subject of the research before the end of the observational study; thereby causing interference.
7. The return method had to be simple and efficient.
8. The analysis had to meet the research aims.

As one of the aims was to elicit opinion on hazard types, it was necessary to consider the use of open ended questions. The use of such questions in self administered questionnaires is quite rare, mainly because most are analysed using quantitative, statistical methods (Sudman and Bradburn, 1982; Blaxter et al., 1996c; Hague, 1993). Open ended questions were possible in this questionnaire because the analysis was mainly qualitative. Although there was a risk that they could result in a low return rate, the belief was that professionals with an interest in the subject might be eager to respond and would provide high quality data. They were interspersed with and integrated into closed questions, so that those respondents unable to provide more qualitative information would at least have the opportunity to contribute to some quantitative data.

The final design and layout can be seen in appendix B1. There were two versions, each tailored to the site at which it was deployed. The only differences were in the instructions for returning the completed document within the introduction and a small change to the wording of the final question which asks about the length of the respondents experience in healthcare.

The introduction was written to engage with a wide range of professionals at all levels. Some very simple instructions were provided on how to complete the questionnaire and return it.

The first question was used to collect some professional demographic data and allowed the respondent to make a selection from eight listed professions or to specify their profession if not listed.

Question two asked: "*How many times have you ever seen patients harmed or badly affected in some way as a result of Oxygen Therapy?"* and was the first to offer an open option within which to expand on the reasons for problems experienced. This was an attempt to gauge frequency of harm and to collect descriptions of the more serious hazards.

The third question listed nine previously identified hazards and asked: "*In those instances where there have been problems with Oxygen Therapy, even if no-one has been harmed, what proportions were from the following causes?"* Six options were given: None, Very Few, Few, Many, Most or All. The question also allowed for additional hazards to be specified and for the same selection of proportional occurrence for these. This was linked directly to the third aim of this study, which was to estimate the frequencies at which these hazards might occur.

Question four asked: "*Approximately how many instances, even where no-one was harmed, have you seen in the last 12 months where there have been problems with Oxygen Therapy?"* Further details were requested in a similar way as question two. The intention was to assess the frequency and nature of all witnessed incidents. It was limited to 12 months to provide a time frame to help the respondent answer the question.

Question five asked: "*Do you think current guidelines are adequate in ensuring patient safety during Oxygen Therapy?"* Six options were offered: Not at all, Poorly, Partly, Adequately, Mainly or Completely. Further comment was invited. The aim of this question was to get some idea of whether guidelines were seen as useful as well as whether respondents were aware of them. This together with the two open questions, were intended to provide some idea of the attitudes of professionals towards patient safety with oxygen therapy.

Finally, question six asked: "*When did you start working in healthcare? Please include your time as a trainee.*" This, combined with the information from question one, would help establish the type of professional with the most interest in the subject of the research. This information would be useful in the selection of panel members and participants for the later formal hazard analyses. A points system was used to score the level of involvement from each respondent. A point was given for each question answered and extra points awarded for additional information supplied.

The questionnaire was piloted at a workshop held during the monthly meeting of senior nurses at Bedford Hospital and a number of changes were made based on their feedback. Further comment was received from colleagues at Cranfield University and members of the local research ethics committee, who were researchers experienced in the use of questionnaires.

Changes made included a re-written introduction emphasizing the respondent's anonymity and more clarity regarding the purpose of the questionnaire. The questions on numbers of incidents witnessed had previously contained check boxes against value ranges. These were removed and replaced with a single box for the respondent to write their own number, removing possible bias and memory influence. The order of the questions was also changed along with the wording of the final question, which was possibly still slightly confusing for some.

Distribution commenced at Bedford Hospital on the 20th October 2006 with another delivery on the 27th, resulting in a total of 809 deployed copies. Three deliveries totalling 930 copies were made to Stoke Mandeville Hospital on the 9th, 13th and 19th of March 2007. Each department or ward manager was

personally handed a number of questionnaires according to how many staff they managed. The purpose and scope of the research was discussed with them and a request was made for them to hand out the questionnaires.

By the 3rd of May 2007, 210 completed questionnaires were returned, representing 12.08% of the 1739 distributed in total. Each of the 2000 copies printed cost just under £0.14, resulting in a total of £274.36 and a cost per return of £1.31.

4.3.2 *Questionnaire Results*

Questions two and four were the main vehicles for the collection of hazard themes and these were added to by the last part of question three and the open section of question five. The results from these were combined to produce the graph of Figure 4-5, which provides a count of the number of times the particular theme was identified.

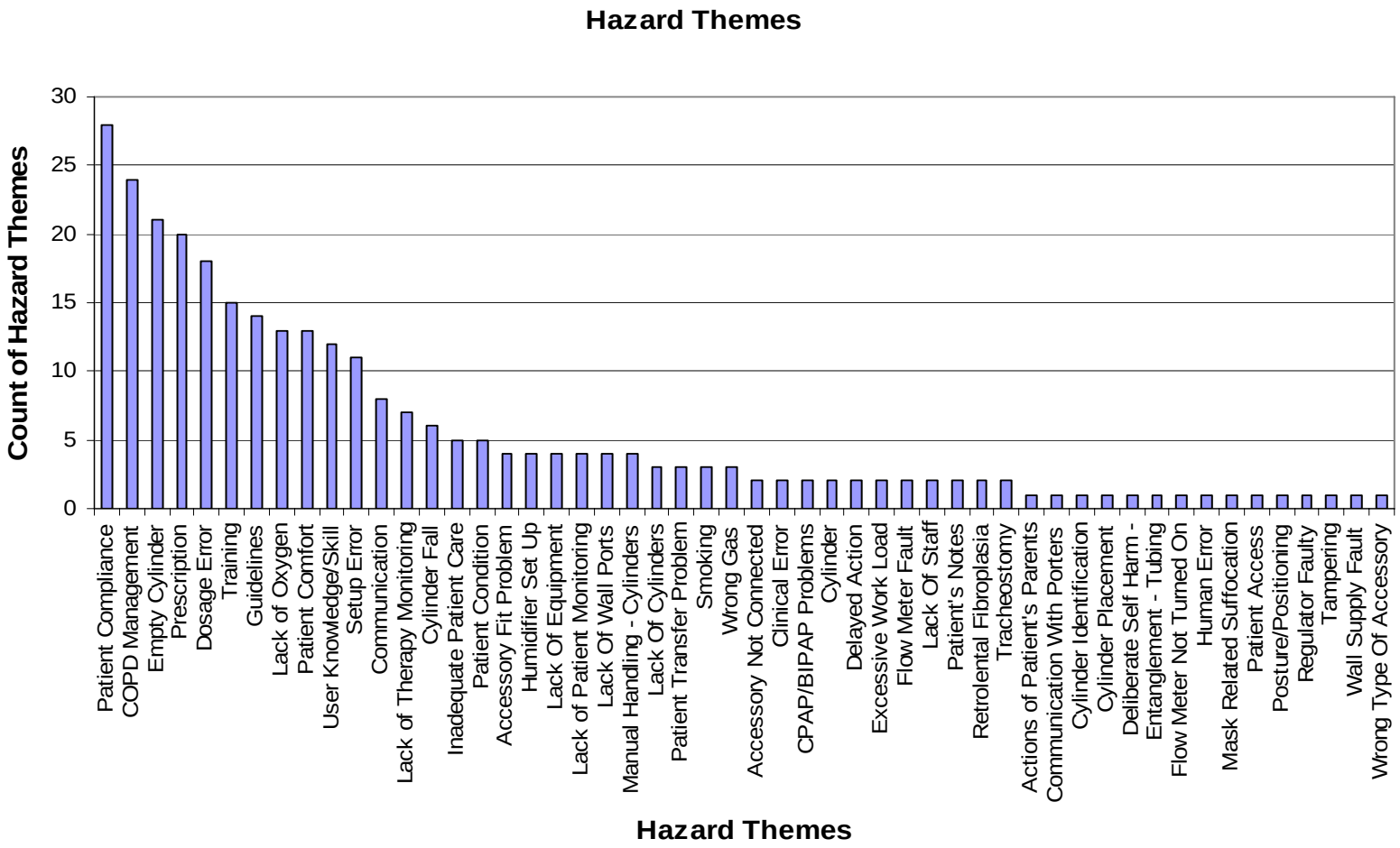

Figure 4-5 Hazard Themes and Occurrences.

A total of 54 hazard themes were identified from the 293 separate statements in the responses. This suggests an occurrence rate for individual professionals of between one and twenty eight, with an average of about six per year. The most frequently identified were problems with patient compliance, concern over the management of patients with Chronic Obstructive Pulmonary Disease (COPD) and the matter of empty cylinders. Some of the clinical and operational issues with high frequencies were problems with prescriptions (either not made out or incorrectly written), dosage errors, staff training and inadequate guidelines.

Many of these were indicated as possible sources of harm. Question two asked specifically about harmful events and all the themes identified from the responses to this question are listed in Figure 4-6, along with the number of times they were mentioned.

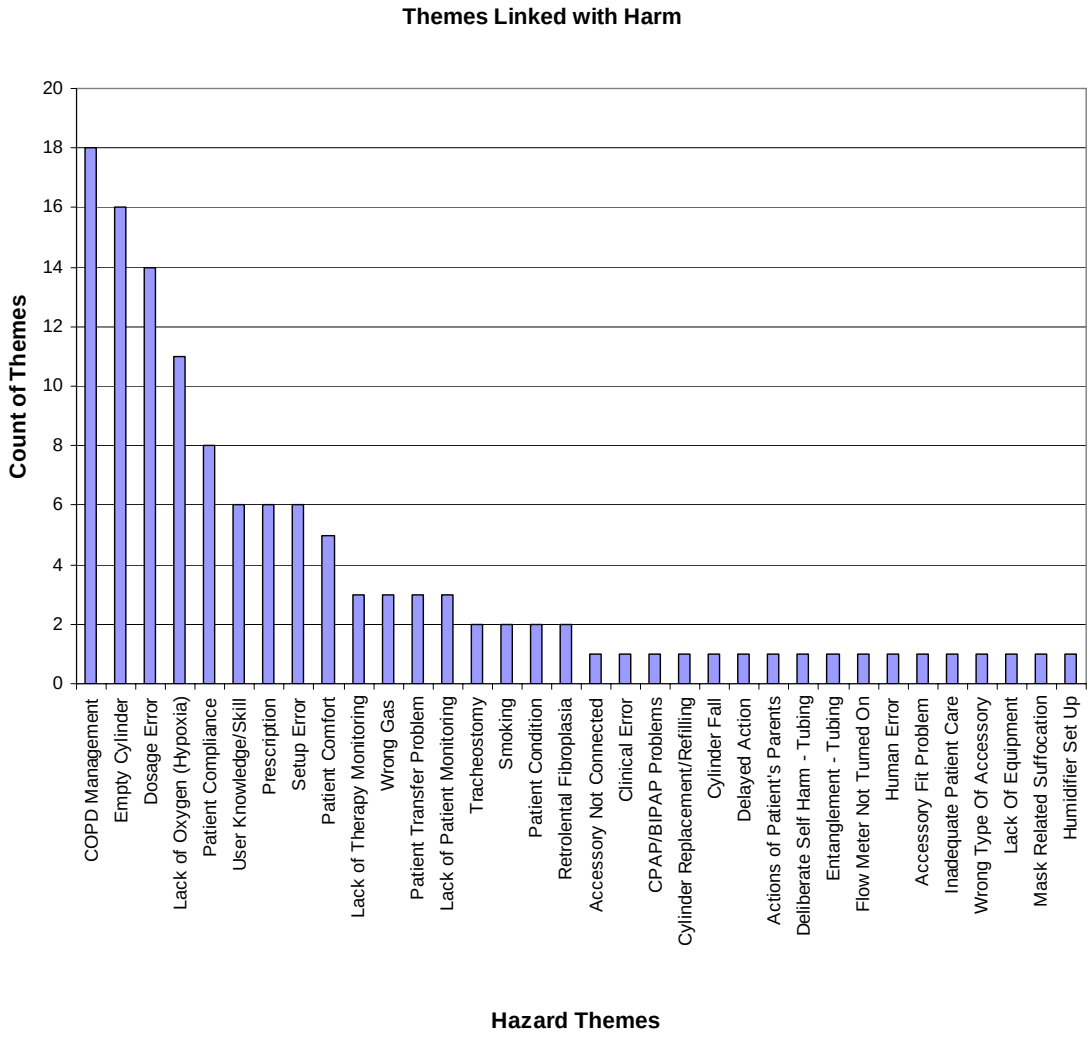

Figure 4-6 Themes Identified as Harmful

The percentages for the themes common to these two questions were summed in order to apply a weighting to those linked with patient harm. These numbers were then divided by 200 (the total denominator from two percentage scales) to provide a proportional risk value as shown in Figure 4-7, effectively ranking the categories by perceived risk.

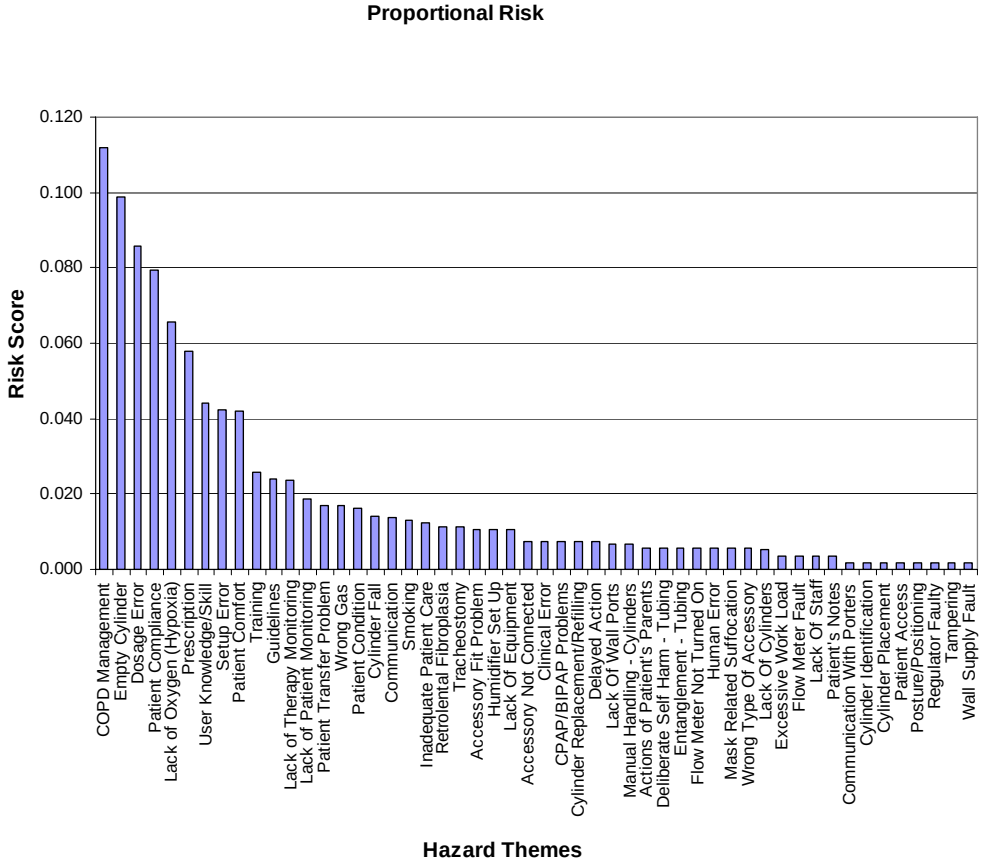

Figure 4-7 Proportional Risk

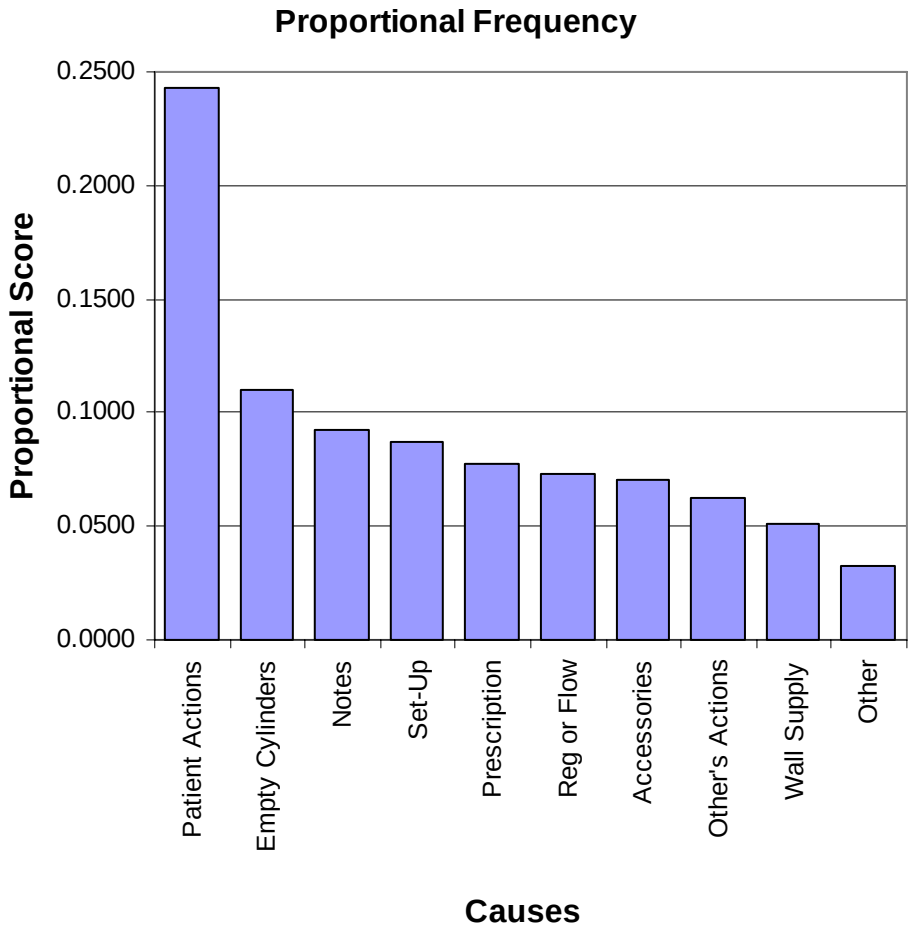

Figure 4-8 Proportional ranking of frequencies of causes

Question three provided the opinions of respondents on the proportional frequencies of nine pre-identified hazard themes. The matrices used for the calculations can be found in Appendix B2. The indication as shown in Figure 4-8 is that events caused by patients' actions are by far the most frequent while problems with the wall supply are the least. Those categorized as "Other" are addressed separately within the previous analysis of proportional risk from identified hazard themes.

The responses to question five which asked about the usefulness of guidelines produced a varied response. Approximately nine percent of respondents indicated that they were unfamiliar with any guidelines and most of these were therefore unable to comment on their adequacy.

Of all respondents, 190 (90.5%) either made a selection from the choices given as in Table 4-7, or provided comment on the adequacy of guidelines (Table 4-8). Both these tables express these counts as a percentage of the 190 responses to this question. Issues with the prescribing of oxygen, training of clinical staff and the communication of guidelines were the most commonly expressed. Many comments made it clear that guidelines on their own were insufficient and needed to be backed up with training and clearly presented in an accessible format.

Table 4-7. Opinions on Guidelines.

Adequacy	Count	%
Adequately	63	33.2%
Mainly	40	21.1%
Partly	32	16.8%
Poorly	17	8.9%
Completely	14	7.4%
Not at all	11	5.8%

Table 4-8. Themes Indicated From Comments on Guidelines.

Themes	Count	%
Unfamiliarity with guidelines	17	8.9%
Prescriptions	9	4.7%
Training	7	3.7%
Communication of guidelines	7	3.7%
Administering the Therapy	3	1.6%
Misinformation on COPD	2	1.1%
Patient/Therapy Monitoring	1	0.5%
Unrealistic guidelines	1	0.5%

Table 4-9. Respondent Demographic.

Profession	Count	%	Ave Involvement	Ave Years in Healthcare
Other Clinical	1	0.5%	16.0	21.04
SAS Doctor	4	1.9%	15.5	8.63
Trainee Doctor	24	11.5%	15.2	5.67
Technologist	1	0.5%	15.0	18.78
Qualified Nurse	109	52.4%	14.5	16.61
Therapist	7	3.4%	14.3	12.86
Student Nurse	13	6.3%	13.9	3.03
CSW	25	12.0%	13.4	7.81
Consultant	14	6.7%	13.3	24.28
Midwife	10	4.8%	11.6	15.82

In Table 4-9, the professions of the respondents are sorted by average involvement score. The number of responses from each professional group is shown alongside the proportion this represents, expressed as a percentage of the total responses. The average number of years spent in healthcare for each of these professions is also shown.

The spread of professions responding to the research follows the pattern one would expect to be representative of the overall professional demographic in a hospital, suggesting that they are all equally concerned with patient safety. This is further supported by the involvement score which had a standard deviation of only 1.29 across professions.

This information was used to build the contextual reference and would also be used later in the research to provide denominator data and aid in planning the formal hazard analyses.

4.4 Combined Analysis

4.4.1 *Hazard List*

The hazard themes from the observations and the questionnaire were combined to form a hazard analysis in which the three main hazard components; Hazardous element, Initiating mechanism(s) and Threat(s) were identified. The list was further rationalized and each hazard was given an identification number to aid later cross-referencing. This preliminary hazard analysis is available in Appendix C1. There were 684 observed events and 54 questionnaire themes which were distilled to 119 distinct hazards. The distillation was similar to that used for the observed themes, in which the common hazardous elements were identified and named through an iterative process.

4.4.2 *Context and the Common Frame of Reference*

During the formulation of the hazard list, there emerged the perception of the system as having three sub systems: Supply, Therapeutic and Clinical. These were used as the starting point for the production of a system diagram, which is provided in Figure 4-9. The diagram shows each sub-system and identifies the components within each. The components and sub-systems are linked by arrows indicating both direction of oxygen flow and influence between them. Component attributes which may have an influence on system safety are also defined.

Further to this, the management of the system was considered within a task analysis which is shown in Figure 4-10, with eight main elements in three horizontal strata. These are related to the clinical processes and functions, while a fourth contains the management influences.

Both these diagrams were heavily based on the information contained in the results from both the observations and the questionnaire. They were verified through discussion with clinicians including Consultant Anaesthetists and Senior Nurses.

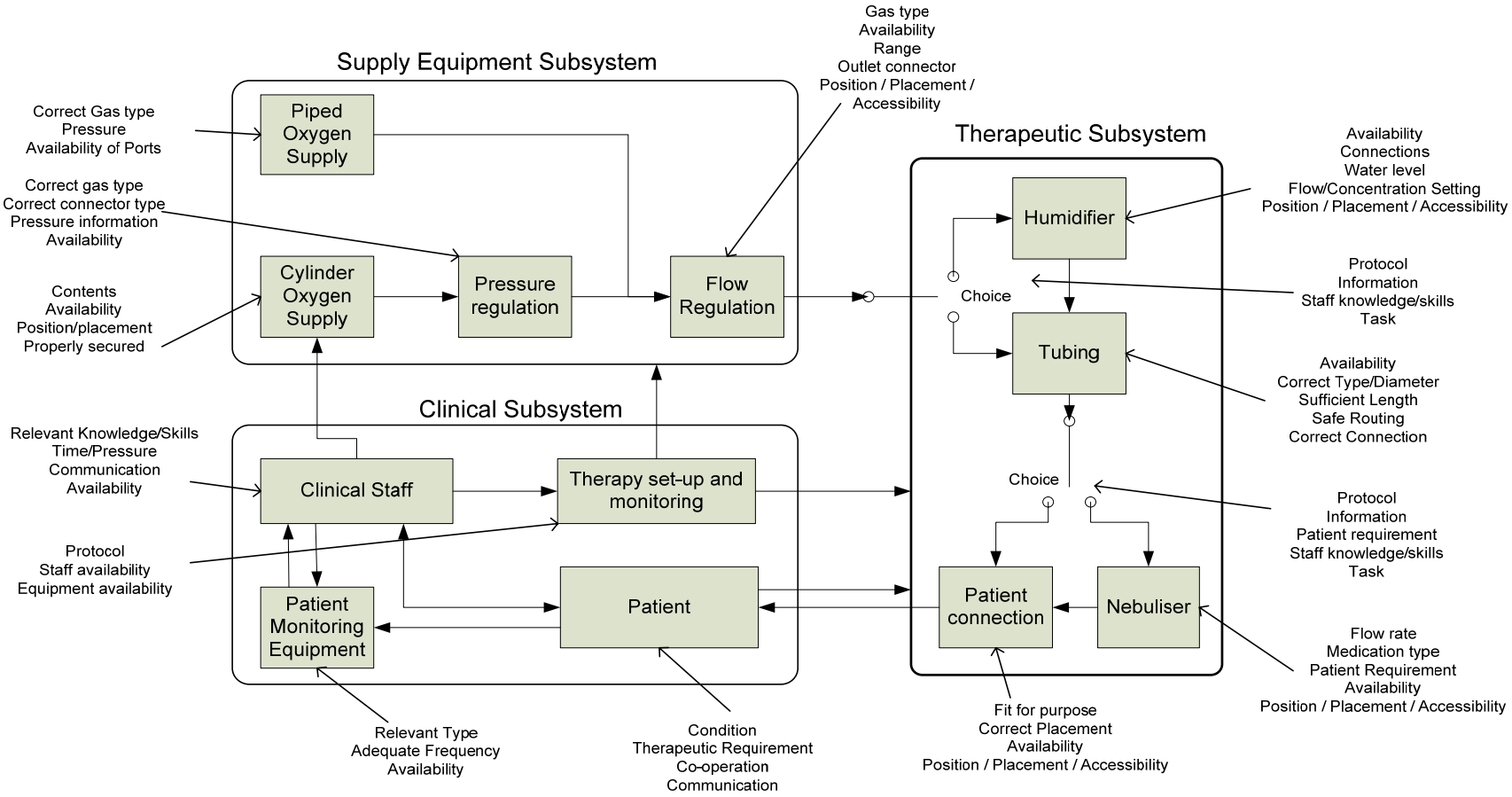

Figure 4-9. Oxygen Therapy System Block Diagram.

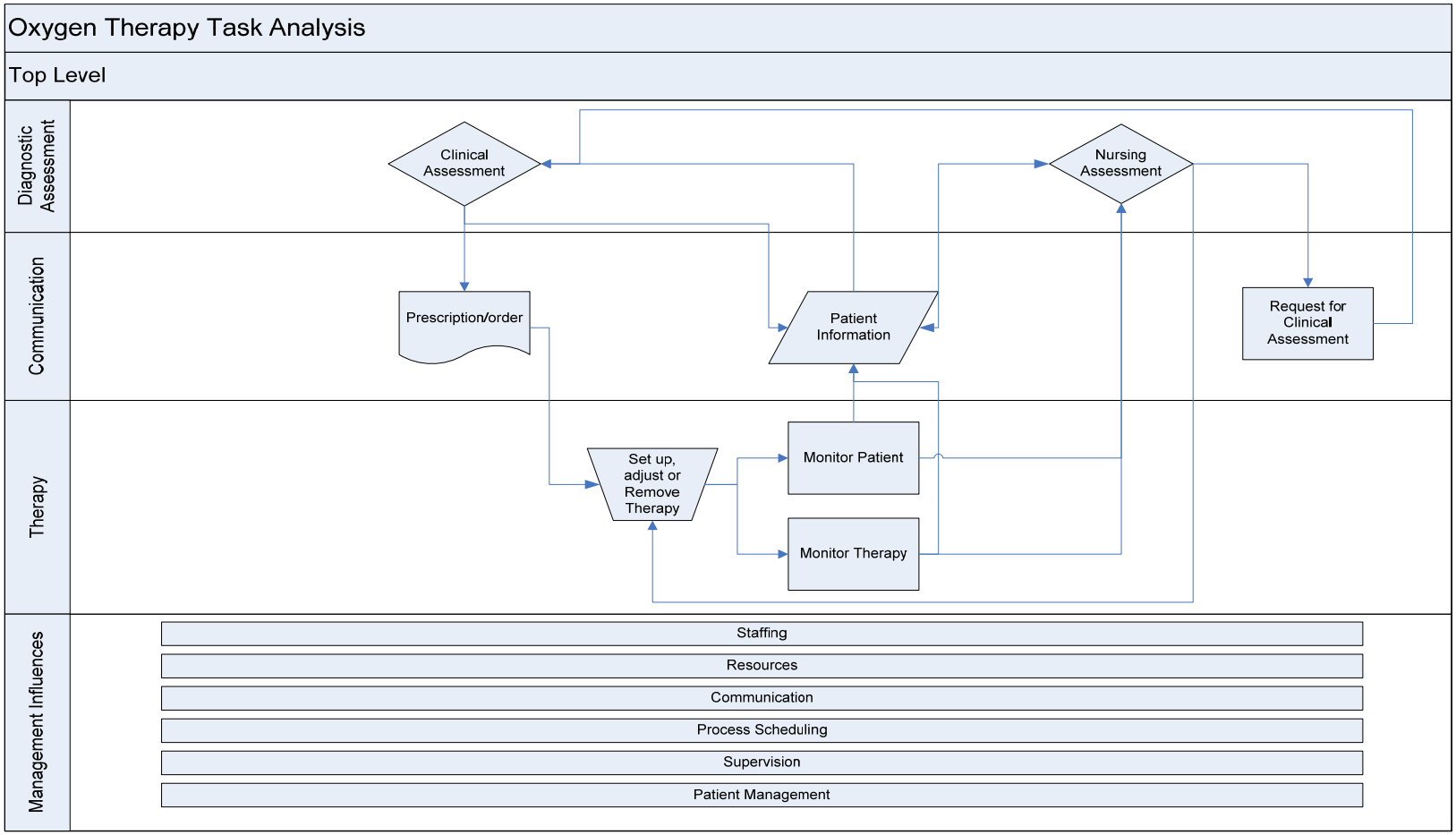

Figure 4-10. Oxygen Therapy Task Analysis.

4.5 Conclusions

4.5.1 *The Observations*

The objectives for the observational study were met as follows:

1. *To identify and define hazards by:*

    a. *Observing events surrounding the administration and monitoring of oxygen therapy including the interactions between staff, patients, visitors and the oxygen therapy equipment.*

This was achieved by making use of a complimentary combination of "unstructured" observations recorded by narrative text and "structured audits" recorded by pro-forma. These were combined in a database to allow the identification of hazards from events through qualitative thematic categorization.

    b. *Assessing the threat posed by the identified hazards through the consideration of possible outcomes of observed events.*

The events were analysed for possible outcomes, which were judged to be adverse, neutral or favourable by making use of thirteen pre-defined consequences. Six percent of the observed events were seen to have resulted in an adverse outcome.

Using these two types of information, an analysis was constructed, defining 250 hazards by hazardous element, initiating mechanisms and threats.

2. *To obtain an estimate of the denominators for this research by:*

    a. *Identifying methods commonly used on hospital wards for the delivery of oxygen therapy and how these are set up, monitored and managed.*

    b. *Calculating an approximation of the number of patients receiving oxygen therapy daily and the frequency of methods of administration.*

Making use of mainly audit data, it was found that simple, standard (or Hudson) masks and nasal cannulae (or specs) together constitute about 70% of the accessories used for oxygen therapy on wards. Many other accessories are also used and there appears to be some confusion over the issue of when the therapy should be humidified. Problems with the management of cylinders were also observed.

It was estimated that approximately eight percent of patients admitted to hospital receive oxygen. This concurs with other UK based studies and when applied to hospital episode statistics, indicates that about 1.3 million inpatients receive oxygen daily. If combined with the finding that six percent of these patients may experience a problem with oxygen therapy, it leads to the possibility that over 80,000 patients are affected by an adverse incident per year.

Many more positive observations were also made which aided in the definition of the therapy system and promoted an understanding of its context.

4.5.2 *The Questionnaire*

The objectives of the questionnaire study were met as follows:

1. *To identify hazards experienced by practitioners.*

The use of four open ended questions facilitated the collection of hazard themes from the experience of healthcare professionals. A total of 293 separate statements were made resulting in the identification of 54 hazard themes. These were combined with those gained from the observations to produce a hazard analysis.

2. *To estimate how often practitioners experience cases of harm to patients due to failures of oxygen therapy.*

The open questions mentioned above were embedded within closed questions which supplied some data on the frequencies of adverse events. These pointed to an average of approximately six adverse events experienced by individual professional per year. The themes, ranked by frequency are shown in Figure 4-5.

The results from questions two and four were used to produce a proportional risk score for the hazard themes. The results shown in Figure 4-7 indicate that there is most concern about the management of patients with COPD, the problem of cylinder depletions and incorrect dosage levels. Of least concern are the issues of equipment failures and problems with piped supplies.

3. *To rank some previously identified hazards by proportional frequency.*

Question three addressed this aim directly and the results are presented in Figure 4-8. These closely agree with the combined risk estimate from questions two and four, with the addition of general setup errors, which was also indicated as a prominent source of risk.

4. *To gauge the attitudes and perceptions of practitioners with regard to patient safety with oxygen therapy.*

The combination of responses to the question about guidelines and the demographic and involvement data indicated a general consensus over the issue of patient safety with oxygen therapy. No particular professional group showed more concern than the others and all were interested in aiding patient safety.

Most agreed that guidelines are inadequate on their own and need to be supported through training and communication.

4.5.3 *The Combined study*

In addition to the objectives of the individual studies, there were two combined aims:

1. *To construct a hazard list using the combined data from both studies.*

This was achieved by combining the themes identified in both studies and constructing a hazard analysis. The result is available in Appendix C1. Hazards

are defined by stating the hazardous elements, considering possible initiating mechanisms and evaluating possible threats.

2. *To construct a common frame of reference for later use in the formal hazard analyses by:*

    a. *Identifying all the components of the oxygen therapy system.*

    b. *Gaining familiarity with the practical issues faced by those involved in the administration of oxygen therapy on wards.*

These were both addressed through the knowledge and appreciation obtained from the immersion experienced while conducting the observational research. This is expressed in the production of a block diagram of the system (Figure 4-9), which divides the system into three sub-systems, defines the components within each and assigns attributes to each component. A further definition of the practical processes is provided in the form of the task analysis presented in Figure 4-10.

The following chapter describes the use of retrospective analysis of reported incidents to both validate and add to the hazard list constructed through the observations and questionnaires.

Chapter 5 Finalising the Hazard List: Making Use of Incident Reports.

Abstract

This chapter describes the validation and refinement of the hazard list created in the previous chapter. It continues to address the first research aim (section 1.1.1) within the first phase of the project as described in section 1.2. This forms the point labelled '*Incident Report Review*' on the triangle labelled '*Combined Evaluation Data*' in Figure 1-2 and Figure 1-3.

There were 5,755 incidents relating to oxygen therapy reported across England and Wales during 2006. These records, containing descriptions of the reported events, were reviewed and categorised. This was achieved through the use of a specifically designed taxonomy and an electronic form linked to a database.

The results were used to provide a qualitative assessment of the validity of the previously constructed list of 119 hazards based on the results of observations and questionnaires, which also provided the basis of the taxonomy. The high level of similarity between the previous list and the results from this research endorsed the hazard list. New hazards were also identified through the incident reports and these were added to the list, bringing the total number of hazards to 188.

The novel use of a measure of relevance for each hazard identified through the incident reports enabled a risk assessment to be attached to 71% of the hazards in the full list. This aggregated hazard list and risk assessment would be used in the next stage of the research to evaluate the contribution from three hazard analysis methods.

5.1 Introduction

5.1.1 *Background*

Following construction of the list of 119 hazards in Appendix C1, which was produced from the observational research and questionnaire, it was felt necessary to both validate and amend its content by making use of historical data. Two options were considered; the review and analysis of patient complaints, or the same of incident reports. The latter were chosen as they were thought to be the most likely to clearly indicate hazards.

Clinical incident reports contain as a minimum, a description of the circumstances and events surrounding an incident. In the UK, they are recorded in two ways: Locally through an internal reporting system and nationally through the Reporting and Learning System (RLS) held by the National Patient Safety Agency (NPSA). Many local systems are now totally electronic, although there are still some trusts with a paper based form which is transcribed to a database. These local records are sent via custom software to the NPSA where they are processed and entered into the RLS database.

Local reports were initially briefly explored as a data source while a request was made to the NPSA for an analysis of data from the RLS. The resulting NPSA report (see Appendix D.1) was compelling, as was the prospect of reviewing national data. An agreement was therefore made with the NPSA for access to anonymised data.

Interest in this research was expressed by the Research Associate from the NPSA who wrote the initial report mentioned above and by a group of five Consultant Anaesthetists. A research group, which included these and the author, was thus formed for the review of national incident reports pertaining to oxygen therapy.

5.1.2 *Taxonomy*

The development of a taxonomy as the basis of a categorization framework for these incident reports was undertaken and there were various influences on this. In chapter seven of "*Patient Safety*" (Walshe and Boaden, 2006), Dovey and colleagues give an account of how to go about developing a taxonomy and the limitations and pitfalls in using them (Dovey et al., 2006).

Examples of taxonomies in the field of Patient Safety include the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) Patient Safety Event Taxonomy (Chang et al., 2005) and the Australian General Occurrence Classification (Dovey et al., 2006). Both are built into custom software packages. These were briefly examined for applicability to this study, but were found to be too complex and wide ranging. It was felt that they were beyond the scope of this research as they are generalized systems used for the analysis of all types of adverse events. As a more specific taxonomy was required, it was necessary to construct it from first principles.

Section 5.2.2 describes the process of development of both the taxonomy and the incident reviewing software. Two trials were undertaken, evaluating the combination of the taxonomy and software, before attempting the full study described in section 5.2.7.

5.1.3 *Purpose*

Incident reports have historically been used in healthcare primarily to record the specifics of an incident in order to have a full account for the purposes of litigation and assessment of responsibility or error. The Department of Health has been working towards moving the emphasis of incident reporting away from blame and closer to learning for the purpose of prevention (Department of Health,Sir Ian Carruthers OBE and Pauline Philip, 2006; Department of Health Expert Group (Chairman, CMO), 2000; Department of Health, 2002). This part of the research is an example of one way that this might be achieved.

The objective was to construct a hazard list based on the results of the categorization of incidents reported by healthcare professionals. This was expected to go some way towards the verification of the previously constructed hazard list based on the results from the observational and questionnaire research, by comparing it with this one.

After combining the two hazard lists, an aggregated analysis, including a risk assessment of hazard themes was conducted. This was later used in a comparison with the risk assessments produced through the formal hazard analysis methods. It was hypothesized that prospective risk assessments based on expert opinion would be similar to those based on extrapolation from empirical research.

It was believed that most incidents would be the result of a number of hazards in combination, rather than single causes. In order to assess the validity of this belief and to investigate the nature of these causal links, an analysis of patterns of causality present in the categorized data was undertaken.

It was also thought possible that there might be a number of particular circumstances or contexts within which oxygen therapy is administered that could be more hazardous than others. As there were no suitable categorical data already available from the NPSA, the researchers needed to ascertain this from the descriptive text of the report. It was noted that there was uncertainty about whether this could be reliably achieved.

The following aims were identified:

1. To design a taxonomy, specific to oxygen therapy, based on the results from previous research and verified through discussion and trial.
2. To design a method that made use of this taxonomy for reading and categorizing incident reports.
3. To analyse the resulting data for:
    a. Occurrences of hazardous elements.
    b. Risk to patient safety from hazardous elements.
    c. Combinations of hazardous elements.
    d. Specific issues related to the contexts within which oxygen therapy is applied.
    e. Validity; by statistical analysis of interrater reliability.
    f. Efficiency of the technique developed through analysis of time taken per record.
4. To assess the validity of the hazard list previously produced from the observations and questionnaire by comparison to themes identified from incident reports.
5. To construct an aggregated hazard list using the combined data from all three studies, incorporating the risk assessments of hazardous elements.

A total of 5,755 anonymised incident reports covering the calendar year 2006, filtered for terms relevant to oxygen therapy were supplied by the NPSA. These were reviewed by six researchers over the two months between the 1st June and the 31st July 2007.

5.1.4 *Limitations*

Many of the elements in the applied taxonomy were classes of factual occurrences, like “Wrong Gas” or “Empty Cylinder”, which are very often expressly stated in incident reports. Others were more speculative, informed assumptions of contributory factors; like “Patient Condition” or “Institutional Management” which are rarely stated in incident reports. It was understood that no definitive statement could be made about the cause of any incident from reported information without a complete investigation including root cause analysis, interviews and other investigative studies (Woloshynowych et al., 2005; Taylor-Adams and Vincent, 2004). It was however felt that educated assumptions could be used to prospectively consider the types of hazards encountered.

The use of incident reports for researching patient safety risk has been limited in the past, primarily due to valid concerns relating to the reliability of reported incident data (Olsen et al., 2007; Vincent, 2004). Incident reporting is often intended for the purpose of trend analysis, which depends rather heavily on the effectiveness of the taxonomy employed and can also be criticized for being rather subjective. These issues were dealt with in this research by making use of a very specific taxonomy, thus maximizing its effectiveness and through the valid professional opinion provided by the research group. The group members had a high level of expertise and experience in a mix of specialities with a strong clinical knowledge base.

5.2 Method

5.2.1 *Data Acquisition*

The 5,755 incident reports supplied through a data sharing agreement with the NPSA were selected by means of a search of the Reporting and Learning System (RLS) for the United Kingdom using the following criteria:

> “*All incidents, excluding slips, trips and falls, reported between 01/01/2006 and 31/12/2006, in acute and general hospitals or ambulance trusts that contain the text ‘Oxygen’ or ‘O2’ in any of the free text fields.*”

The records were received in the form of two Microsoft Excel spreadsheets containing the raw data and another detailing some of the analysis codes used by the NPSA. These were combined and exported to Microsoft Access database tables for preparation before review by the researchers.

Of most interest for this research, were the free text fields containing the description of each reported incident and the record of actions taken immediately after each event. These were used as the main source of information for the categorization of each incident. There were also two fields relating to outcome; one (Reported Harm) is completed by the person making the initial report, the other (Consequence) is the result of an assessment made by clinical reviewers at the NPSA. These were used for ranking the incidents by outcome and for risk assessments.

5.2.2 *Taxonomy and Software Development*

The taxonomy was developed by taking the hazardous elements identified from the analysis of the observational and questionnaire studies and using the combined knowledge and experience of the research group to identify thematic categories. These were then grouped into three sections; Equipment, Human Error and External.

A method was required to allow the researchers to read and categorize the reported incidents using the developed taxonomy. An electronic form linked to a database was felt to be the most efficient and secure way of presenting both the data and the taxonomy to the readers, while also allowing them to analyse each record.

The database contained a simple structure of three tables. One held the incident reports and another the taxonomy elements linked to the reports by an identity number. The third table contained an activity log, which recorded the time and date of each 'transaction' as well as the incident report accessed.

The data was password protected. Following a logging on procedure, the readers were presented with the single window shown in Figure 5-1. The form contained, in the top left, information about the reader's position in the record list along with the control buttons for navigation within the database. Next to this were the selection lists for case validity (Yes, No or Don't Know) and context (see Table 5-3). Below these, were the text windows for the descriptive fields from the incident report, as well as a notes area for the readers to record their comments.

On the right hand side of the page was the full taxonomy with check boxes to enable the reader to select those elements deemed as contributing to the reported event. Also included were help buttons (containing a question mark icon) to provide the reader with guidance on definitions, use of the form and application of the taxonomy. Further guidance was provided to the readers in a document entitled 'Using the Oxygen Incident Categorization Program' which is available in Appendix D.2.

The software was built using Microsoft Access and Visual Basic for Applications (VBA). Both the taxonomy and the software were trialled before full implementation.

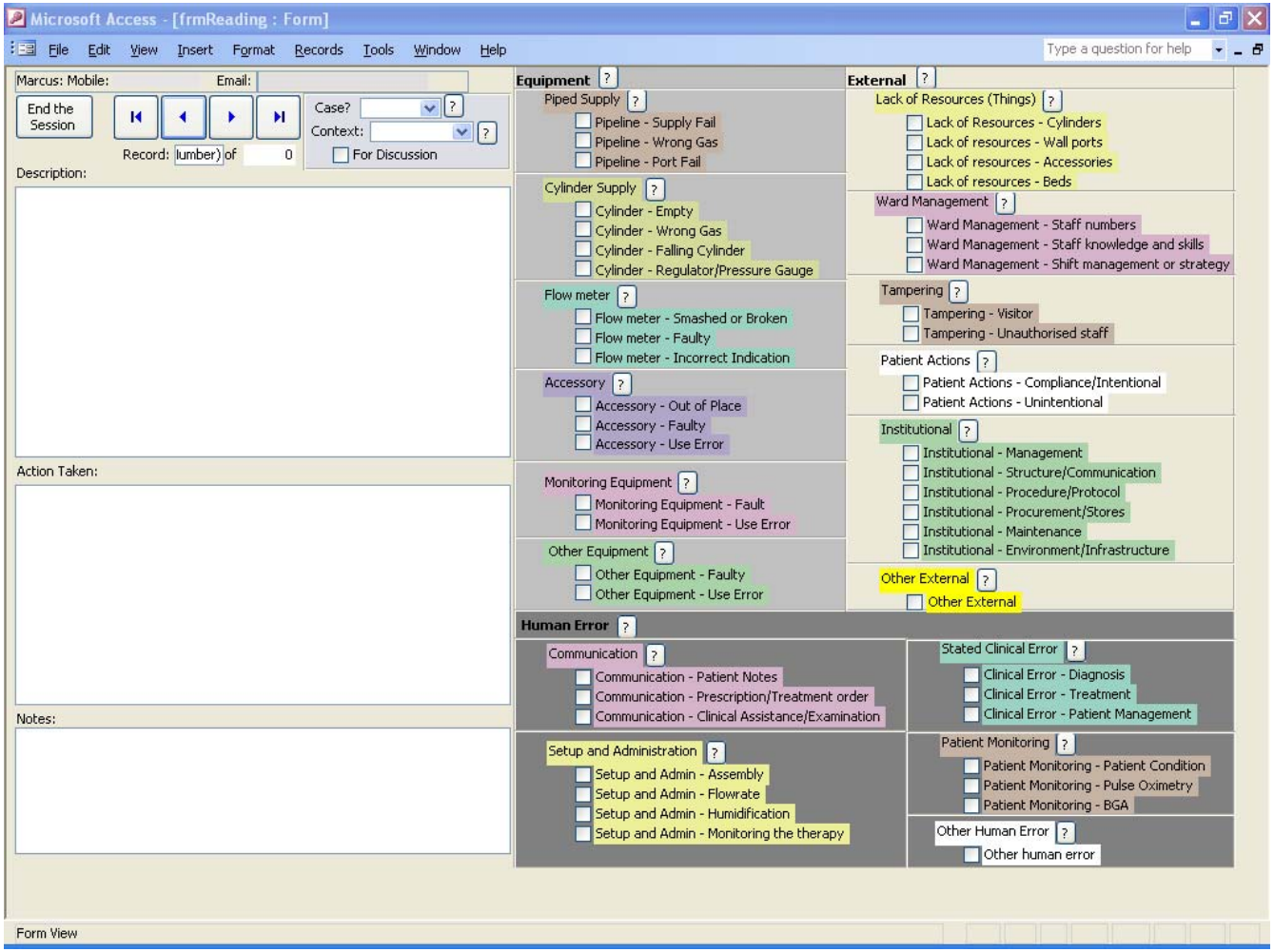

Figure 5-1. The layout of the software application main window.

5.2.3 *100 Record Trial*

There was a concern at an early stage that a detailed taxonomy may cause confusion and thus introduce error. The initial structure (presented in Figure 5-2) was therefore made as wide and unspecific as possible while trying not to be vague. This was assessed in a trial of the electronic form and the taxonomy that made use of the first 100 of the 5,755 records in the NPSA data.

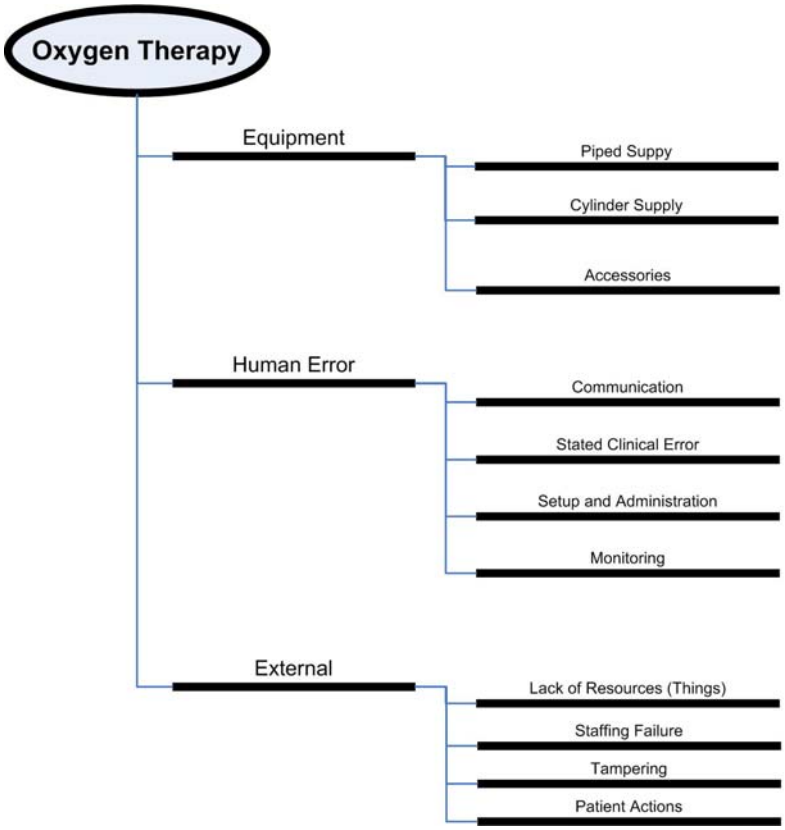

Figure 5-2. The first taxonomy structure.

The 100 trial records were collected and distributed to all seven readers on USB flash memory devices. The readers were given just over two weeks to analyse these records. They were encouraged to make notes about any problems encountered and to express their opinion on the difficulty of the task.

Information gathered automatically by the software on time spent per record was used to assess how long it would take to analyse a full portion of the data (approximately 2,000 records per reader).

The level of agreement on whether any record was a valid case or not was measured using a scoring system that ranked “Disagreement” according to the spread of opinions. There were three possible answers: “Yes”, “No” or “Don’t Know”. For each record, the number of readers that chose each answer was counted.

Table 5-1.Case Agreement Scores

Ans1	Ans2	Ans3	Score
0	0	7	0
0	1	6	1
0	2	5	2
0	3	4	3
1	1	5	4
1	2	4	5
1	3	3	6
2	2	3	7

With three answers and seven readers, disregarding the order, there were eight unique permutations. A score was allocated to each record according to Table 5-1, which shows the number of readers selecting each answer. Full agreement was indicated by all seven readers choosing one answer, and assigned a score of zero. Complete disagreement was assigned a score of seven.

The total case disagreement (*Dgmt*) was obtained by adding the scores across all records. It was expressed as a percentage of the worst case disagreement which was calculated as 7x100 = 700. Since agreement and disagreement are the only two values in this percentage scale, subtracting the percentage disagreement from 100 gives the total percentage agreement as:

$$\text{Percentage agreement} = 100 - \left(\frac{Dgmt}{700} \times 100 \right)$$

Equation 5-1: Case Percentage Agreement.

The agreement of reader's choices of taxonomy elements was analysed using another scoring system. Each element in every record was examined for either "selected" or "not selected". Each instance of either state was counted and the results multiplied to give a score according to Table 5-2. A score of twelve indicates the most disagreement, while a score of zero indicates no disagreement.

Table 5-2. Element Choice Agreement Scores

Selected	Not Selected	Score
7	0	0
6	1	6
5	2	10
4	3	12
3	4	12
2	5	10
1	6	6
0	7	0

The total disagreement (*Dgmt*) for each element was calculated by adding the scores for that element from all 100 records. This was then expressed as a percentage of the highest possible disagreement. (Since there were 100

records under review, the highest possible disagreement score per element was 12 x 100 = 1200.) Since agreement and disagreement are the only two values in this percentage scale, subtracting the percentage disagreement from 100 gives the total percentage agreement for each element.

$$\text{Percentage Agreement} = 100 - \left(\frac{Dgmt}{1200} \times 100 \right)$$

Equation 5-2: Element Percentage Agreement.

Percentage agreement of this type is not as definitive as more accepted statistical tests (Krippendorff, 2003b). In this application however, it is not being used to assess research validity but to assist in a judgment of suitability of the method and is therefore sufficient (Salkind, 2006).

5.2.4 *First Trial Results and Outcomes*

Case agreement was high; with the readers able to agree on which cases were valid for this research 78% of the time. Opinion from the readers was consistent with this result, with most finding the identification of cases fairly simple for most records. There were however, some incidents that contained ambiguous statements making identification more difficult, while others lacked enough detail for a clear choice. These were discussed and strategies developed which were included in the help and guidance notes. The most important of these was to assume a 'worst case' for each incident where outcome or action was unclear. It was felt more important to try to extrapolate hazards rather than to exclude incidents as this is primarily prospective research and not definitive case analysis.

The proportional agreement for the taxonomy elements depicted in Figure 5-3 shows a level of consistency above 70%. Although this indicated that the existing taxonomy structure (Figure 5-2) could be reliably applied, the research group felt that there was insufficient detail to provide a clear enough categorization of all the relevant cases.

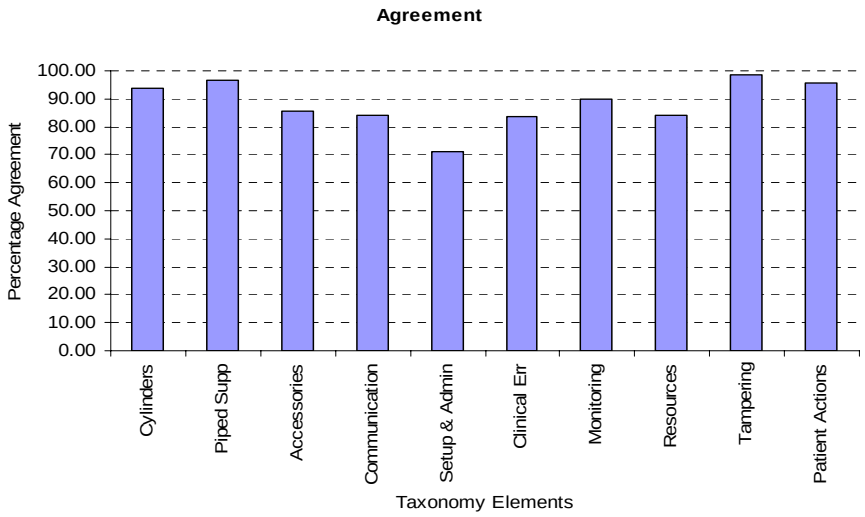

Figure 5-3. Taxonomy element agreement.

All the readers agreed that the software was easy to use. A few modifications were however identified. The first was to display information on the readers' position in the data. Another was an additional start-up window to give the option of starting from the last recorded position or from the beginning of the data file for instances when the researchers were returning to the analysis after closing the form.

An analysis of the average time spent per record can be seen in Figure 5-4 and shows a fairly wide range of investment. On average, it took 80.5 seconds to categorize each record, which meant that it could take a reader on average 45 hours ranging between 22 and 78 hours to complete a set of 2,000 records.

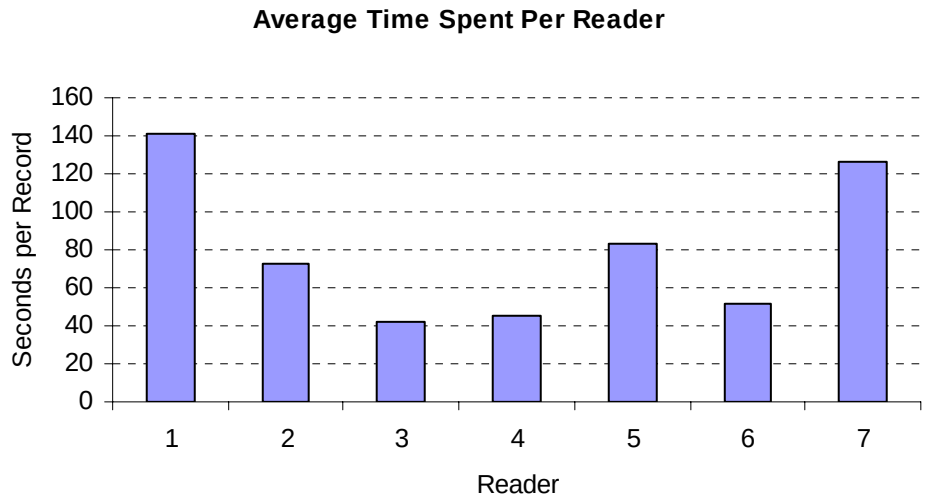

Figure 5-4. Analysis of time spent per record.

5.2.5 *50 Record Trial*

After making the amendments identified after the first trial, which included integration of a more detailed 35 element taxonomy into the form, it was decided that a smaller trial would be sufficient to test the method.

Fifty records were randomly selected from the total population for use as the trial data. Agreement regarding case selection was measured in the same way as previously. Agreement regarding taxonomy choices was also done in a similar way, with the scoring system adjusted to enable assessment of the higher number of choices produced by the larger structure. Both also had to be slightly adjusted to account for the fact that there were now only six readers. One of the anaesthetists in the group left Bedford hospital after the first trial, accounting for the fact that there were seven readers originally and only six from this point on.

5.2.6 *Second Trial Results and Conclusions*

Agreement on case validity increased to 92% compared with 78% on the first trial. This may be attributable to the smaller sample size, clearer guidance on case selection and some acquired learning through experience.

The percentage agreement for the taxonomy elements is shown in Figure 5-5. This indicates an average 90% consistency ranging between 67% and 100%, which is very similar to the result from the first trial. This suggests that the more detailed taxonomy had no detrimental effect on the level of agreement between readers.

The analysis of time taken is shown in Figure 5-6 and is also very consistent with the first trial. An average of 76.6 seconds per record was achieved which equates to an average of 42.5 hours for 2,000 records (ranging between 24 and 57.6 hours).

The final 49 element taxonomy structure shown in Figure 5-7 was agreed after a discussion following this second trial.

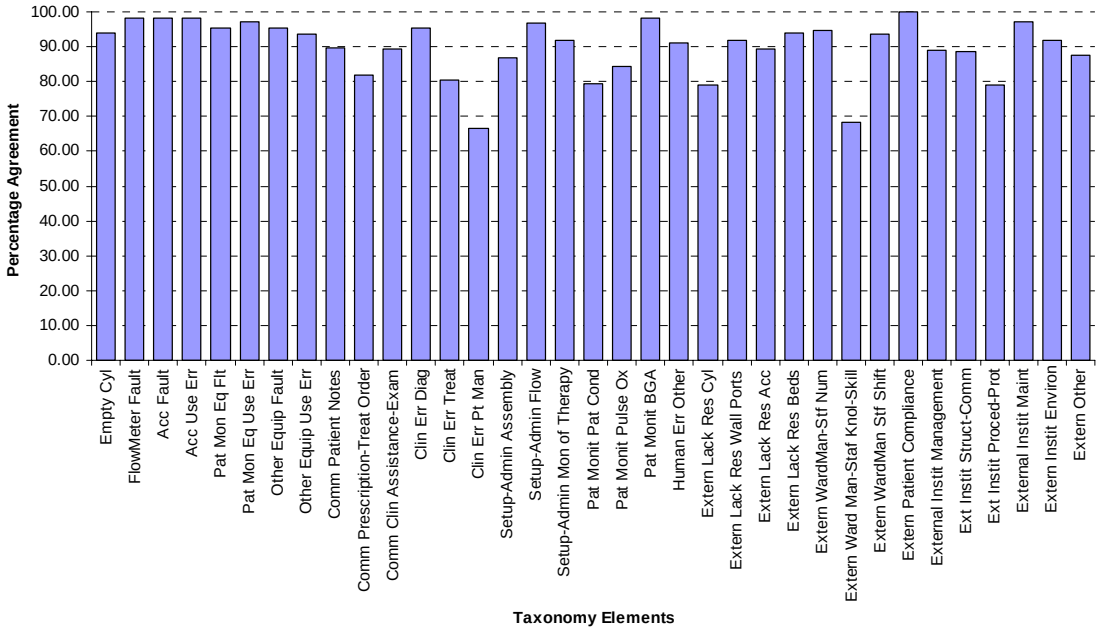

Figure 5-5. Percentage agreement from second trial results

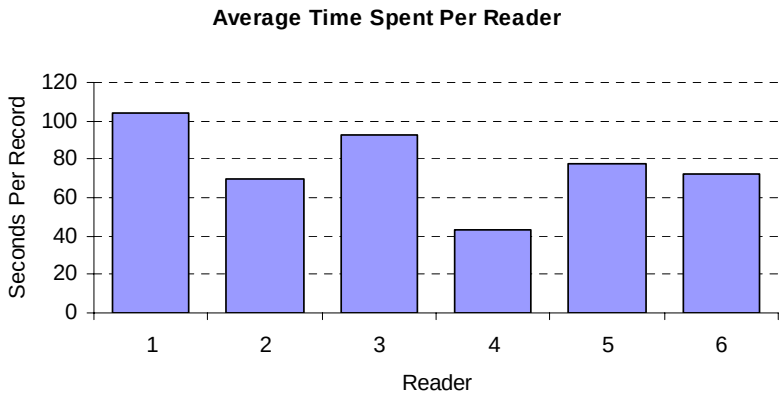

Figure 5-6. Time analysis from the second trial

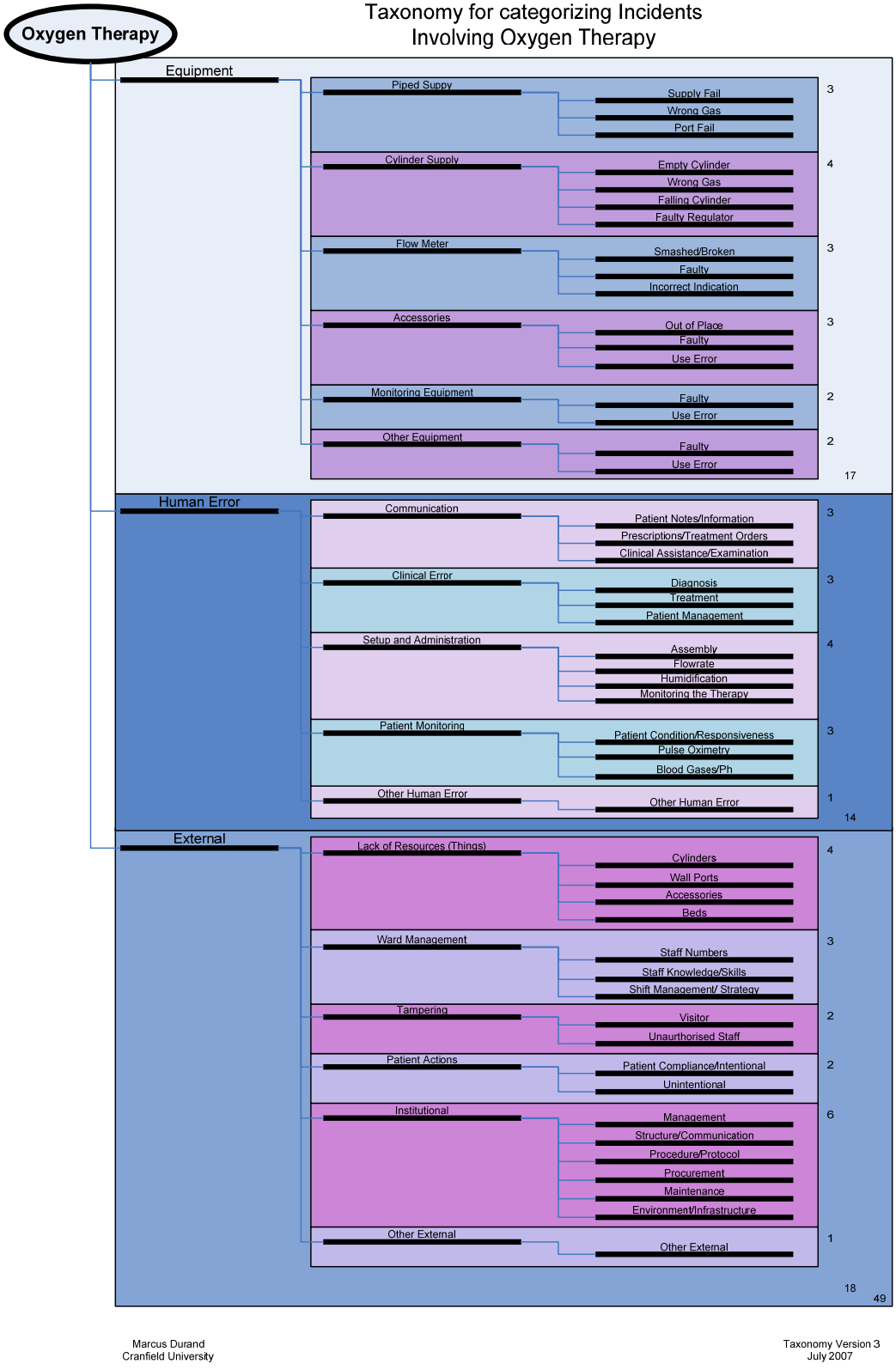

Figure 5-7. The final 49 element taxonomy.

5.2.7 *The live study*

The 5,755 incident reports were split into three groups as shown in Figure 5-8. One hundred and fifty records were randomly selected and placed aside to provide a common set for agreement analysis. This number was chosen as the closest to ten percent of 1,918 (5755/3) that would not extend the data much further than the agreed preferred maximum of 2,000 records.

The remaining 5,605 records were divided into three groups and the 150 previously removed records added to each. Two readers were assigned to a group and given their own copy of the software package with the relevant records embedded. Two of the groups received 2,018 and the third 2,019 records.

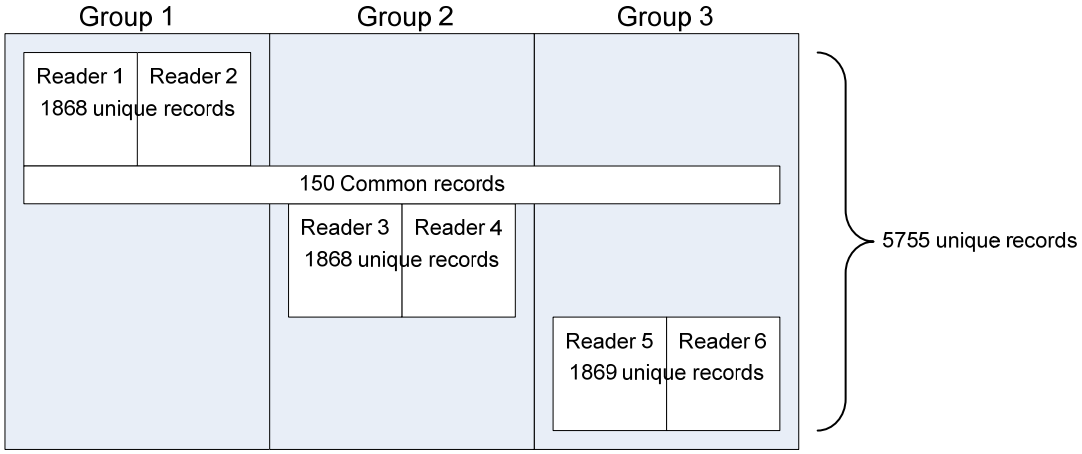

Figure 5-8. Data distribution.

The readers decided on the validity of each incident by application of the following guidance:

> '*Any incident where oxygen therapy was not administered when it should have, failed during therapy or was in some way implicated in the incident. External factors such as other therapies or medications that caused the patient's condition to change and thus affect the therapy should be included. Instances where oxygen therapy was correctly administered as a result of some other incident should not be included*'.

There are various contexts within which oxygen therapy is administered. It was thought possible that there may be a number of these that pose more threat or contain specific, singular hazards. The reader's opinions on the context of each incident were recorded by selection from a dropdown list as detailed in Table 5-3. This list was generated by considering the circumstances within which oxygen therapy is administered. Some of these are positional such as a ward or department, others are situational such as during a transfer or an emergency event. Guidance on these choices was provided to the readers both in the software and the written guidance of Appendix D.2.

Table 5-3: Context list.

Context Description
Don't Know
In a ward
During Internal Transfer
In a Critical Care area
During Recovery
In A & E
In Maternity or during Delivery
In an Ambulance
Other Hospital Areas
Internal Emergency (e.g. Crash Call)
External Emergency (e.g. Car Accident)
Other- Please explain in Notes box

The readers indicated which of the elements they thought might have contributed to each incident by placing a tick in a check box next the relevant elements as shown in Figure 5-1. The software application again automatically collected information on the amount of time spent per record.

5.3 Analysis and Results

5.3.1 *Case Selection and Data Recombination*

A list of valid cases from each of the three groups was compiled by application of the matrix defined in Table 5-4. The lists were then combined, including all cases with a 'Yes' or 'Maybe' result to allow aggregated analysis. The aggregation was achieved by applying an 'OR' function to the tables containing the taxonomy selections for each group, such that if any reader had selected a taxonomy element, that choice went forward to the aggregated data. This follows with the philosophy that even if only one reader identified the presence of a particular element in an event, it was considered to be a valid identification.

Table 5-4. Combined Case Decision

Reader 1	Reader 2	Result
Yes	Yes	Yes
Don't Know	Yes	Yes
No	No	No
Don't Know	No	No
Don't Know	Don't Know	Don't Know
Yes	No	Don't Know

The combination of results from the 150 common records had to be handled separately because it involved the opinions of more than just the two readers in each group. Following the screening of valid cases, the common records were removed from the rest of the data. These were then subjected to a separate 'OR' function process taking into account the choices made by all six readers. The resulting two separate sets of choices were then recombined to form the final data for analysis of identified hazardous elements.

There were 3,078 (53.5%) of the 5,755 records which were judged to be valid cases for this research. 11,288 Taxonomy selections were made, averaging to 3.67 (SD 2.2) hazardous elements per record and a very variable 230.4 (SD 252) selections per taxonomy element.

5.3.2 *Interrater Reliability*

Interrater reliability was measured using Krippendorff's Alpha (Kα) (Krippendorff, 2003a). This is a statistical method based on the Spearman rank correlation. It is similar to Cronbach's Alpha (Salkind, 2006), except that it is able to deal with multiple 'readers' and also takes into account the possible effects of readers making selections by chance (Krippendorff, 2003b). A macro written for the statistical software 'SPSS' was used for the analysis (Hayes and Krippendorff, 2007). Two analyses were made; one across all six readers using the 150 common records and another between the two readers in each group. These were compared to give an indication of the relationship between the common records and the full data set.

Kα computed for the selections on the validity of cases and incident context scored 0.68 and 0.54 respectively, indicating moderate to high reliability. Kα across the 150 common records, ranged from zero (no agreement) to one (full agreement).

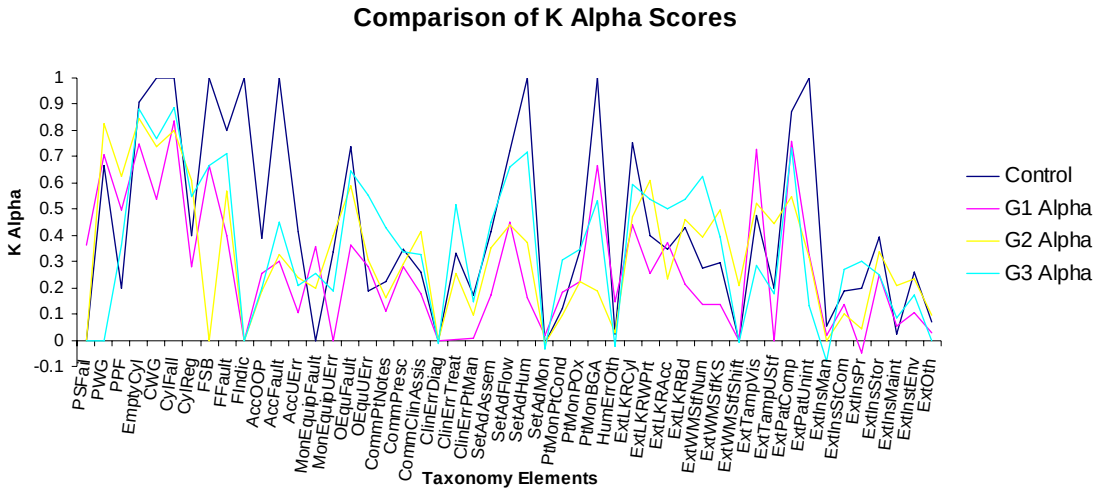

Figure 5-9. Comparison of interrater reliability scores.

A trend analysis comparing the agreement scores for each of the 49 elements is shown in Figure 5-9. The trend lines show similar patterns across much of the graph, suggesting that there are no major differences between the groups. This indicates a high likelihood that the reliability of the full data set is similar to that of the common control group and shows a clear consistency in the use of the taxonomy.

Ten taxonomy elements could not initially be given a reliability score due to insufficient variation between researchers and a low number of occurrences, both of which are vital in an accurate reliability analysis using Kα (Krippendorff,

2003a). This is mainly due to the possibility that the readers made these exactly matching choices by chance or that they may have conferred and thus made the same decisions. Some of these were considered as full agreement in later analyses because the reason for there being no variation was that everyone agreed separately. It was felt that this was a valid assumption given the high level of specific knowledge held by the readers, and not the result of pure chance or collusion between readers.

Some elements had very low reliability scores. This is possibly due to the very few occurrences of some of these and the simple fact that the readers did not agree. The diversity among the group members, combined with the subjective nature of the element selection process may well have contributed to this. The range of reliability scores is seen as advantageous in this context. The prime reason for selecting a diverse group of readers was to elicit a variation in opinion, these variations in reliability indicate that this variation has been achieved.

5.3.3 *Ranking by Element Occurrence*

Some basic descriptive statistics were collected about the frequency of occurrence of taxonomy elements and a ranking by number of occurrences was produced.

A relevance score (Ruthven et al., 2002) was calculated by multiplying the number of occurrences of an element (N_{Haz}) by its average reliability ($\overline{X}_{K\alpha}$) across the three groups. This indicated the probability of its contribution to an incident and was used as a second ranking metric. This was felt to be the closest to a determination of occurrence versus opportunity that was possible with this dataset.

To indicate the difference between the use of frequency and relevance, the ranking by frequency of element occurrence is presented in the left hand column of Table 5-5 and shows '*Procedure/Protocol'* to be most common, followed closely by '*Staff Knowledge and skill'* then '*Clinical error – Patient Management'*. In contrast to this, the ranking by relevance (calculated from the reliability scores) on the right hand side of the same table illustrates that '*Staff Knowledge and Skill'* is now placed most prominently, with '*Empty Cylinders'* moved up from 14th to 2nd place and '*Clinical Error - Patient Management'* demoted from 3rd to 16th position.

It would seem that the effect of bias from individual readers has been removed by the use of this metric, producing a more normalized result. If, for example, a single reader had attributed almost every incident to '*Institutional Management*' then the frequency for this element would have been very high. If the other readers did not agree well with this observation, then the relevance score for that element would be low, effectively cancelling out some of the bias introduced by the single reader. This example is well evidenced in Table 5-5.

Table 5-5. Taxonomy elements ranked by frequency (Left) and relevance (Right).

Taxonomy Elements **By Frequency**	**Freq**	Taxonomy Elements **By Relevance**	**Rel**
Institutional - Procedure/Protocol	1124	Ward Management - Staff knowledge and skills	358.2
Ward Management - Staff knowledge and skills	1045	Cylinder - Empty	219.1
Clinical Error - Patient Management	806	Lack of Resources - Cylinders	164.6
Clinical Error - Treatment	636	Clinical Error - Treatment	164.3
Other human error	601	Patient Actions - Compliance/Intentional	121.8
Institutional - Structure/Communication	495	Institutional - Procedure/Protocol	110.9
Patient Monitoring - Patient Condition	474	Setup and Admin - Assembly	99.7
Institutional - Management	447	Patient Monitoring - Pulse Oximetry	98.1
Patient Monitoring - Pulse Oximetry	370	Communication - Prescription/Treatment order	96.9
Lack of Resources - Cylinders	328	Lack of resources - Accessories	95.4
Communication - Prescription/Treatment order	320	Patient Monitoring - Patient Condition	92.6
Setup and Admin - Assembly	306	Other Equipment - Faulty	90.4
Setup and Admin - Monitoring the therapy	304	Institutional - Structure/Communication	83.6
Cylinder - Empty	265	Communication - Clinical Assistance/Examination	74.9
Lack of resources - Accessories	258	Setup and Admin - Flowrate	68.8
Communication - Clinical Assistance/Examination	245	Clinical Error - Patient Management	68.2
Communication - Patient Notes	240	Lack of resources - Wall ports	64.4
Institutional - Maintenance	234	Institutional - Procurement/Stores	61.4
Institutional - Procurement/Stores	220	Other Equipment - Use Error	58.2
Institutional - Environment/Infrastructure	196	Communication - Patient Notes	56.2
Patient Actions - Compliance/Intentional	179	Ward Management - Staff numbers	50.0
Other Equipment - Faulty	170	Lack of resources - Beds	48.1
Other External	160	Cylinder - Falling Cylinder	44.6
Accessory - Out of Place	157	Patient Monitoring - BGA	35.1
Other Equipment - Use Error	153	Accessory - Out of Place	33.6
Accessory - Use Error	140	Institutional - Environment/Infrastructure	33.5
Lack of resources - Wall ports	138	Other human error	30.7
Setup and Admin - Flowrate	133	Cylinder - Regulator/Pressure Gauge	30.2
Ward Management - Staff numbers	130	Pipeline - Wrong Gas	30.1
Lack of resources - Beds	119	Monitoring Equipment - Fault	29.7
Monitoring Equipment - Fault	110	Institutional - Maintenance	27.5
Patient Actions - Unintentional	95	Accessory - Faulty	26.7
Patient Monitoring - BGA	76	Cylinder - Wrong Gas	26.5
Accessory - Faulty	74	Accessory - Use Error	25.6
Cylinder - Regulator/Pressure Gauge	63	Patient Actions - Unintentional	24.7
Pipeline - Wrong Gas	59	Setup and Admin - Humidification	16.7
Clinical Error - Diagnosis	54	Tampering - Visitor	16.4
Cylinder - Falling Cylinder	53	Pipeline - Port Fail	15.3
Ward Management - Shift management or strategy	47	Flow meter - Faulty	14.0
Setup and Admin - Humidification	40	Monitoring Equipment - Use Error	7.6
Cylinder - Wrong Gas	39	Other External	6.4
Monitoring Equipment - Use Error	39	Tampering - Unauthorised staff	4.2
Tampering - Visitor	32	Pipeline - Supply Fail	3.2
Pipeline - Port Fail	31	Ward Management - Shift management or strategy	3.1
Pipeline - Supply Fail	27	Flow meter - Smashed or Broken	2.7
Flow meter - Faulty	25	Flow meter - Incorrect Indication	0.0
Tampering - Unauthorized staff	20	Clinical Error - Diagnosis	-0.2
Flow meter - Smashed or Broken	6	Setup and Admin - Monitoring the therapy	-2.9
Flow meter - Incorrect Indication	5	Institutional - Management	-10.0

5.3.4 *Risk Analysis*

Risk assessments of the form *Risk = Likelihood x Harm* were carried out on each hazardous element. As no direct indication of likelihood was available, the relevance score calculated previously was used as a measure of the probability of each element's contribution to an incident.

Even though a generalised proportional determination had been made in paragraph 4.2.8, this could not be applied to the individual taxonomy elements as the actual number of occurrences is unknown. There are two reasons for this: Firstly this study used reported events, which cannot be assumed to indicate overall rates of occurrence. Secondly, the readers were asked to be somewhat speculative and not rely entirely on 'reported fact'.

The weighting values from Table 5-6 were applied to each occurrence of an element within an incident. The weighted values were then added to produce a harm score per element.

Table 5-6 Harm Weighting

Harm	Value
Death	10
Severe	6
Moderate	3
Low	1
No Harm	0

A risk score was then calculated using the relevance score and multiplying this by the weighted score of reported harm. Where N_{Haz} is the number of occurrences of a hazard and $\overline{X}_{K\alpha}$ is the average agreement for that hazard:

$$Risk = (N_{Haz} \times \overline{X}_{K\alpha}) \; Harm\ score$$

Equation 5-3: Element Risk.

Risk analyses of this type are useful as an indication of a quantitative ranking of hazards, but lack the qualitative judgments necessary to make decisions on whether to take a certain course of action. The intention in this study was not to make recommendations on action, but to aid in understanding the relationship between hazards in terms of possible harm and likelihood of occurrence. It was therefore felt adequate to use a context free score to make this determination.

Application of the risk analysis based on the relevance of a taxonomy element rather than pure frequency, produced the ranked results listed in Table 5-7. The relevance scores were scaled in order to remove negative values and to produce a minimum relevance of one. This was mainly to prevent negative risk scores, which are meaningless.

Table 5-7. Risk analysis by taxonomy element

Categories	Codes	Harm	Relevance	Risk
Ward Management - Staff knowledge and skills	WMSK	1007	369.2	371784.4
Clinical Error - Treatment	CET	730	175.3	127969.0
Institutional - Procedure/Protocol	IPP	1023	121.9	124703.7
Clinical Error - Patient Management	CEPM	936	79.2	74131.2
Patient Monitoring - Patient Condition	PMPC	587	103.6	60813.2
Patient Monitoring - Pulse Oximetry	PMPO	445	109.1	48549.5
Institutional - Structure/Communication	ISC	415	94.6	39259.0
Lack of Resources - Cylinders	LRC	199	175.6	34944.4
Cylinder - Empty	CE	144	230.1	33134.4
Setup and Admin - Assembly	SAA	242	110.7	26789.4
Communication - Prescription/Treatment order	CPT	248	107.9	26759.2
Communication - Clinical Assistance/Examination	CCE	279	85.9	23966.1
Lack of resources - Accessories	LRA	201	106.4	21386.4
Patient Actions - Compliance/Intentional	PACI	138	132.8	18326.4
Other human error	OHE	435	41.7	18139.5
Communication - Patient Notes	CPN	228	67.2	15321.6
Other Equipment - Use Error	OEUF	159	69.2	11002.8
Other Equipment - Faulty	OEF	90	101.4	9126.0
Setup and Admin – Flow rate	SAF	111	79.8	8857.8
Lack of resources - Wall ports	LRWP	108	75.4	8143.2
Institutional - Procurement/Stores	IPS	112	72.4	8108.8
Institutional - Environment/Infrastructure	IEI	159	44.5	7075.5
Lack of resources - Beds	LRB	112	59.1	6619.2
Accessory - Out of Place	AOP	145	44.6	6467.0
Institutional - Maintenance	IMC	131	38.5	5043.5
Accessory - Use Error	AUE	130	36.6	4758.0
Ward Management - Staff numbers	WMSN	77	61.0	4697.0
Patient Monitoring - BGA	PMBG	92	46.1	4241.2
Patient Actions - Unintentional	PAU	93	35.7	3320.1
Monitoring Equipment - Fault	MEF	77	40.7	3133.9
Pipeline - Wrong Gas	PWG	71	41.1	2918.1
Setup and Admin - Monitoring the therapy	SAM	270	8.1	2187.0
Cylinder - Falling Cylinder	CFC	39	55.6	2168.4
Other External	OE	119	17.4	2070.6
Accessory - Faulty	AF	48	37.7	1809.6
Cylinder - Regulator/Pressure Gauge	CRP	31	41.2	1277.2
Setup and Admin - Humidification	SAH	36	27.7	997.2
Cylinder - Wrong Gas	CWG	22	37.5	825.0
Clinical Error - Diagnosis	CED	71	10.8	766.8
Monitoring Equipment - Use Error	MEUE	35	18.6	651.0
Ward Management - Shift management or strategy	WMSS	43	14.1	606.3
Tampering - Visitor	TV	15	27.4	411.0
Pipeline - Port Fail	PPF	14	26.3	368.2
Institutional - Management	IMT	365	1.0	365.0
Flow meter - Faulty	FF	13	25.0	325.0
Pipeline - Supply Fail	PS	16	14.2	227.2
Tampering - Unauthorized staff	TUS	8	15.2	121.6
Flow meter - Incorrect Indication	FII	7	11.0	77.0
Flow meter - Smashed or Broken	FSB	4	13.7	54.8

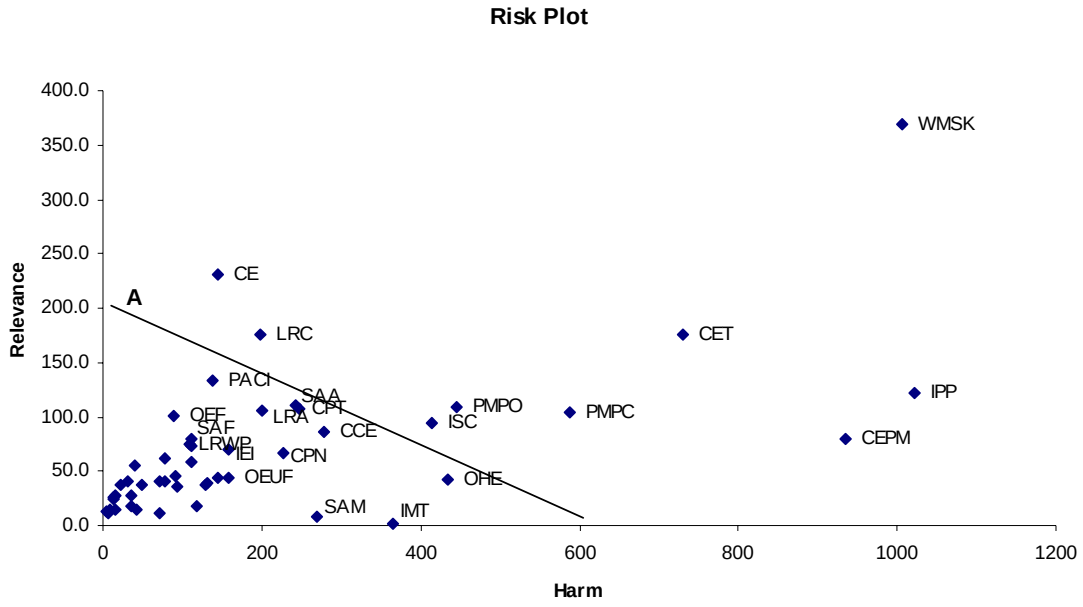

Figure 5-10 Scatter plot of Harm versus Relevance

Figure 5-10 shows the risk relationship between the elements and gives a slightly different relational meaning to risk than simply ranking by score as in Table 5-7. For the sake of clarity, only those elements that can be individually identified are labelled. Table 5-7 provides a key to the category codes used. The fifteen elements with the highest risk scores also fall above or near the line drawn between the 50% points on each axis of Figure 5-10. This line, labelled '*A*', indicates an assumed approximate '*As Low As Reasonably Practicable*' (ALARP) zone. This is a term commonly used in Hazard Management referring to an area on a graph such as this where efforts need to be made to reduce the risk as much as possible. Any items beyond this need the most urgent attention. There was no analysis made in order to choose the position of this line other than looking at the graph and selecting an approximate point where the top fifteen elements would be addressed with the most urgency.

Three elements in Figure 5-10: '*Ward Management - Staff knowledge and skills', 'Institutional - Procedure/Protocol' and 'Clinical Error - Patient Management'*, followed closely by '*Clinical Error – Treatment'* are indicated as the highest risk, especially as they are associated with high levels of harm. All the other labelled categories fall near the ALARP line.

5.3.5 *Element Combinations*

It was recognized early in the research that most incidents would be the result of a number of contributory hazards. An examination of combinations of taxonomy elements, looking for patterns of contributory factors leading to death or serious harm was made through selective sorting.

The full results of the selective sorting of elements to look for patterns of occurrence can be found in Appendix D.3, Table D.3-1.

The most common combinations contained the elements:

- *Institutional - Procedure/Protocol*
- *Clinical Error - Patient Management*
- *Ward Management - Staff knowledge and skills*
- *Clinical Error – Treatment*
- *Patient Monitoring - Patient Condition*
- *Patient Monitoring - Pulse Oximetry*

The highest number of deaths was attributed to '*Clinical Error – Treatment*', which accounted for six fatalities.
'*Clinical Error - Patient Management', 'Patient Monitoring - Pulse Oximetry', 'Communication - Clinical Assistance/Examination'* and *'Lack of resources – Beds',* were each associated with three deaths.

5.3.6 *Context*

Unlike the choices of taxonomy elements, the opinions on the apparent contexts within which each reported incident may have occurred could not be combined for aggregated analysis and were therefore examined separately. A similar method to assessing harm per element was used to score the harm related to each context. This was then used together with the number of occurrences to assess the risk per context. The one with the highest risk was examined more closely, looking for any specific hazards or prominent issues. This is still a very polarized, quantitative view of risk applied to context categories. It remains a 'context free' assessment because there is no subjective judgement being made.

The frequency of occurrence, harm score and risk value per context are shown in Table 5-8. Frequency is a simple count of occurrences. The harm score was calculated using a matrix method employing the same weighting as the assessments per element (see Table 5-6). The risk value is a scaled multiple of frequency and harm.

Table 5-8. Context risk.

Context Description	Freq	Harm	Risk
In a ward	1799	1692	14092
Don't Know	921	617	2631
During Internal Transfer	761	553	1948
In a Critical Care area	447	313	648
Other Hospital Areas	264	138	169
In an Ambulance	214	180	178
In A & E	205	181	172
In Maternity or during Delivery	213	151	149
Internal Emergency (e.g. Crash Call)	137	193	122
Other- Please explain in Notes box	117	75	41
During Recovery	95	32	14
External Emergency (e.g. Car Accident)	12	18	1

As expected, the context with the highest frequency and risk was that of therapy applied '*In a Ward*'. It is also evident from the high number of times researchers

chose '*Don't Know*' that it is very difficult to attribute context to many reported incidents. This is one of the limiting factors in the use of 'pure' empirical research for hazard analysis.

As the ward context was already under examination, the one with the next highest risk, '*Internal Transfers*', was discussed and some further detail sought. Three researchers spent one week re-examining as many as possible of the 844 incidents in association with transfers for origin and destination. 133 records were analysed. The origins were mainly wards (36.8%) or Accident and Emergency (19.5%). Destinations were most commonly wards (32.3%), critical care areas (19.5%) or medical imaging departments (17.3%). Table 5-9 shows the three most common routes taken during internal transfers.

Table 5-9. Most common transfer routes.

Route	Count	% of Total
Ward to Imaging	15	11.3
Ward to Critical Care	14	10.5
A&E to Ward	14	10.5

5.3.7 *Time and Effort*

Analysis of time spent was made by first removing any transaction records over six minutes long as this was assumed to be the longest a reader was likely to be actively assessing a record. This was felt to be a reasonable assumption because most of the incident descriptions were very short. Anything longer was most likely due to leaving the form active while not engaged in the research. The remaining data was analysed for mean time per record and total time spent.

The researchers were also asked to provide some feedback on their experience of using the software and taxonomy.

It was projected from the results of the second trial that it would take an average of 42.5 hours to complete 2,000 records, with readers spending approximately 76.6 seconds per record. The breakdown of time taken shown in Table 5-10 indicates that the analysis of the incident reports took less time than expected, with an average of just 27.5 Hours total or 49 seconds per record.

Table 5-10. Time analysis

Group	Tot Hrs	Ave Hrs	Ave Seconds Per Rec
1	37.8	18.9	33.7
2	58.9	29.5	52.6
3	68.1	34.1	60.7
Combined	164.8	27.5	49.0

Table 5-11. Analysis of activity

Group	Reader	Total Time (Hrs)	Seconds per Record	Total Element selections	Difference	Group Average Ka
1	1	18.4	32.9	928	743	0.28
	2	19.3	34.5	1671		
2	3	26.7	47.7	2176	62	0.33
	4	32.2	57.4	2238		
3	5	48.1	85.8	3246	1617	0.36
	6	20.0	35.7	1629		

As shown in Table 5-11, reader one tried to be very precise in assigning hazardous elements according to 'reported fact' rather than expressing opinion. This was not the intention of the study and was possibly the result of their being unable to attend many of the pre-study meetings. As a result, since in most cases evidence was scant, this reader made the fewest selections and spent less time per record. Interestingly; this seems to have had only minimal effect on the interrater reliability for that group. Reader five spent the most time on the task and recorded the highest number of selections. This too seems to have had no detrimental effect on the reliability scores.

Most readers found the method and the taxonomy easy to use and all stated that they had gained knowledge and insight from the experience. Most felt that they had completed the task quicker than expected, but admitted that it had at times been tedious. All reported that they had encountered a few records where there were themes not identifiable through the taxonomy. These were recorded in the notes section of the reading form.

5.3.8 *Hazard List Validation and Aggregation*

The hazard list constructed from the results of the observations and questionnaire was validated using a qualitative approach, where the taxonomy elements were linked to the hazard themes identified. An analysis was made using a comparison table and a partial 'traffic light' indication. Red was used to show that a theme was not identified through a particular method, while orange indicated partial identification.

The notes made by the readers regarding hazards not identified through the taxonomy were qualitatively assessed and the emerging themes added to those from the taxonomy. The entire list was then made into one hazard analysis including, where possible, the results from the risk assessments.

The result of the comparison of taxonomy elements to themes from the existing hazard analysis can be seen in Appendix D4, Table Appendix D4-1, which also includes the calculation of the final risk score for each hazard. It lists in each column, the hazards identified during the observational research alongside the hazard themes from the questionnaire study and the taxonomy elements, with those relating to each other in each row. A red cell indicates that no corresponding hazard, hazard theme or taxonomy element could be identified for that row and an orange cell indicates partial similarity.

The risk scores from the questionnaire and the incident report studies are summed to produce the 'Risk Sum' value in the last column. This final value was carried to the aggregated hazard analysis in Appendix D5, Table Appendix D.5-1. A risk score was calculated for 71% of the hazards using the results from the questionnaire and incident report studies. Most of the observed hazards were covered by the questionnaire and incident report studies. As expected however, both these studies identified additional hazards not seen during the observational research.

The final aggregated hazard analysis is presented in Table Appendix D.5-1. A total of 188 hazards were identified through further distillation of the combined analyses. The table is arranged by alphabetical listing according to the system diagram of Figure 4-9. A colour coding was assigned to indicate risk categories according to the values in Table 5-12. These represent risk scores of above 1.5 times the mean (High), 0.5 times either side of the mean (Moderate and Minor) and below 0.5 times the mean (Low). Fifty five hazards (29%) could not be risk assessed due to a lack of information regarding likelihood and harm.

Table 5-12. Risk analysis summary

Risk Category	Value	N	%
High	> 0.2494	26	14%
Moderate	> 0.1663 < 0.2494	32	17%
Minor	> 0.0831 < 0.1663	34	18%
Low	< 0.0831	41	22%
Un-Assessed		55	29%
Total number of hazards:		188	100%

5.4 Conclusions

A taxonomy, developed through a design process which included two comprehensive trials, was applied to 5,755 incident reports in order to identify possible contributory hazardous elements within valid cases. The structure of the taxonomy (see Figure 5-7) was informed by a combination of the results from previous observational and questionnaire research along with the high level of experiential knowledge of the research group. The software for making use of the taxonomy was validated through the same trial process applied to the taxonomic structure.

The results of the final categorization of the incident reports were tested for reliability using Krippendorff's Alpha (Kα) and showed mixed results but were in general acceptable because a degree of diversity is advantageous in this context and was in fact the purpose of having a diverse research group. This was also used to calculate the probability of an elements' contribution to an incident by way of an estimation of relevance based on frequency of occurrence and the reliability score. The relevance and an estimation of harm calculated using a weighted scoring method were applied together to produce a risk analysis for each hazardous element in the taxonomy (see Table 5-7. Risk analysis by taxonomy element).

The objective to create an aggregated hazard analysis was achieved with a high level of success. The previously constructed hazard list was verified to a large extent by the high degree of similarity of identified hazards (see Appendix D4). The hazard list was also amended and appended to, based on the additional identifications made from the incident reports and the knowledge gained on the nature of oxygen therapy and the related hazards.

The final aggregated hazard analysis (see Appendix D5), was arranged according to the system diagram constructed from the knowledge gained during the observational and questionnaire research (Figure 4-9). The hazard analysis was later used to assess the validity of each of the formal hazard analysis methods applied in the next chapter.

The risk assessment of hazard themes and the investigation into the combinations of hazardous elements creating an incident were used along with the results from the questionnaire study to produce a risk score for 71% of the identified hazards. Not all the hazards could be risk assessed as some of them were identified in addition to those defined through the taxonomy or from the questionnaire study. Knowledge on the nature of the hazards related to oxygen therapy was gained by looking closely at the contexts within which events occurred and how hazardous elements combined to create an incident.

The efficiency and difficulty of this method for defining hazards was examined through a combination of time spent and opinions from the researchers. It was concluded that this method makes the analysis of a large number of incident reports possible in a relatively short period of time and was fairly easy to apply in most cases.

Chapter 6 Evaluating the Formal Hazard Analysis Methods.

Abstract

This chapter describes the second and third phases of the research as described in Chapter 1, section 1.2. The application of Failure Modes and Effects Analysis (FMEA), Fault Tree Analysis (FTA) and Hazard and Operability Analysis (HAZOP), using the common frame of reference consisting of the system diagram (Figure 4-9) and the Task analysis (Figure 4-10) is discussed. The hazard analysis methods were compared to each other in terms of process and presentation. Their results were compared to the combined hazard list described in the previous chapter in order to assess their applicability to ward based healthcare. This process is depicted in Figure 1-2 in Chapter 1.

FMEA achieved 61% system coverage followed closely by FTA with 60%, while HAZOP only achieved approximately 44.6%. Although useful risk assessments could be attached to both the FMEA and the HAZOP results, FTA could not be used to its full potential when assessing probabilities of events. FTA did however provide clear indications of causality and event linkage which could not be achieved with the other two methods.

It was generally found that these methods presented added value through the provision of:

- Information for system modification.
- Valid, accurate risk assessment.
- Identification of hazard barriers and safeguards.
- A formal method for the communication of results.
- A vehicle for documented learning.

The two most striking conclusions were that:

1. The systems and processes definitions required by these methods provide a valuable opportunity for learning and the capture of tacit knowledge.
2. An enduring means for the capture and dissemination of knowledge on hazards and risk is provided that can be continually updated and used for the formulation of strategies for safety and quality improvement.

6.1 Introduction

The large number of existing Hazard Analysis methods makes the choice of which to use a daunting one. As outlined in Chapter 2, only Failure Modes and Effects Analysis (FMEA) appears to have been assessed (DeRosier et al., 2002; Linkin et al., 2005) or, to a large extent, had any published account of its use in healthcare (Van Tilburg et al., 2006; Fechter and Barba, 2004).

This evaluation was undertaken to assess the applicability of these methods to healthcare. This was accomplished by comparing the results from each method against those produced from the empirically based research. Judgements were also made about the usefulness of the information presented and whether some basic requirements for the identification of actions to prevent or mitigate incidents were met.

6.1.1 *Evaluation Aims*

The following aims were identified for this evaluation:

- To select a small number of hazard analysis methods from the seven previously short-listed.
- To conduct hazard analyses using each of the chosen methods in turn, all based on the system diagram of Figure 4-9 and the Task analysis flow chart of Figure 4-10.
- To compare the results of each with the hazard analysis constructed previously from empirical research.
- To asses the level of system coverage achieved by each method.
- To discuss the presentation and usefulness of the information produced by the analyses.
- To discuss the techniques for the assessment of risk or priority employed by each of the methods.
- To discuss the overall ‘usability’ of each method.

6.2 Hazard Analysis Methods

6.2.1 *Selecting the Methods for Evaluation*

The choice of methods to evaluate was dictated to a large extent by those which were accessible to the researcher. Seven had previously been shortlisted, as described in Chapter 2, based mainly on the fact that information about them and experience on their application was available within Cranfield University. These were: FMEA, FTA, ETA, HAZOP, SWIFT, HEART and THERP.

Both HEART (Williams 1986) and THERP (Kirwan, 1996) are very numerical and require the assessor to make judgments on “*Performance Shaping Factors*” (PSFs) and ‘*Error Producing Conditions*’ (EPCs) which are built into the methods. It was felt that the specificity of these methods, the fact that they do not themselves identify hazards and their extremely quantitative nature made

them unsuitable for this research. This therefore left FMEA (including its two variants; Healthcare Failure Modes and Effects Analysis (HFMEA) and Failure Modes and Effects Criticality Analysis (FMECA)), FTA, ETA, HAZOP and SWIFT. A more detailed comparison of these methods was required to further refine the choice. Some basic criteria for their selection were defined as follows:

1. The methods needed to be able to take into account a wide range of hazard domains, e.g.:
    - *Equipment failure*: There was a range of both permanent hardware and disposable accessories that had to be assessed.
    - *Human factors*: Therapies are not yet specified, ordered and administered by automated systems; there is always a human element in the process at some point. Mistakes and lapses are therefore inevitable and their assessment had to be included. Ergonomics and the equipment interface (Lin et al., 2001; Fries, 2001), shift patterns affecting fatigue and distraction (Narumi et al., 1999), stress and communication were just some of the issues expected to be encountered.
    - *Systems factors*: The robustness of a system can only be assessed if the inter-dependence of every sub system within it can be taken into account (Senders, 2006). This is especially the case with complex systems such as ward based healthcare.
    - *Environmental factors*: Variations in temperature, light levels or noise might affect not only the human elements in a system but also the equipment. The ward layout, bed arrangement and activities in neighbouring beds may also affect how therapies are administered and patients are monitored.
    - *Organizational factors*: Latent errors (Reason, 1999b) are mistakes or omissions within procedures or processes and are often permeated from decisions and actions taken at higher levels within organizations. These are often difficult to detect, but can have disastrous effects.
2. At least one inductive and one deductive method were to be included so that there could be a comparison between the two methodologies.
3. At least one graphically constructed and one tabular method was to be included so that the two general ways of presenting the results of an assessment could be compared.

Table 6-1 was constructed from information gathered about the methods being considered. Their basic structure is described in the first four columns. A subjective judgment on their apparent complexity is included using a scale ranging from 1 (simple) to 5 (highly complex). Any special requirements in order to use them are listed and the final column contains notes referring to the criteria for selection and any other points deemed relevant.

Table 6-1 . The factors for the selection of hazard analysis methods.

Method	Focus	Logic	Style	Complexity 1-5	Special requirements	Notes
FMEA, HFMEA, FMECA	General Healthcare Systems	Inductive	Tabular	2	Some team input	Multiple factors can be included.
						Used for evaluating technology and process.
						Can be used to complete a risk matrix.
						Previous use in healthcare
						Minimal training required
						Systems analysis possible
						Task analysis possible with functional FMEA
						Probabilistic analysis possible
						Can be used to inform FTA , ETA or HAZOP
						Cannot identify hazards from combination failures
						Might not identify hazards not resulting from failure
						Not recommended as sole analysis method
FTA	General	Deductive	Graphical	3	Uses Boolean logic	Multiple factors can be analyzed
					Basic drawing facility	Used for systems analysis
					May need probabilistic data	Used for task analysis
						Possible for single assessor
						Only fault or failure events considered
						Some training and practice required
						Probabilistic analysis possible
ETA	General	Deductive	Graphical and tabular	3	Works best with correct software	Multiple factors
						Used for systems analysis
						Used for task analysis
						Possible for single assessor
						All events considered
						Some training and practice required
						Probabilistic analysis possible
HAZOP	General	Inductive and deductive	Tabular	4	Team based	Multiple factors
					Good leadership	Used for evaluating technology and process.
					Conference facilities	Can be used to complete a risk matrix.
					Co-operation from hospitals	Used for systems analysis
					Some training, but available on campus	Used for task analysis
						Can be linked to other analysis methods
SWIFT	General	Inductive	Tabular	3	Instructional information scarce	Multiple factors
						Used for systems analysis
					Some training and practice required	Not recommended as sole analysis method
						Focuses on cause and effect

FMEA has previously been used in healthcare and seems to be growing in popularity. An evaluation was therefore felt to be timely. A decision had to be made between evaluating FMEA in its more original form, the FMEA modified for healthcare (HFMEA) described by DeRosier et al (DeRosier et al., 2002), or FMECA which includes a system criticality element. FMEA in its original form was chosen so that it could provide an inductive method with a formal tabular presentation and represent a technique with a growing following in healthcare. The result from this evaluation might be used as a benchmark for any future comparison applied to its various 'offspring'.

A difficult choice had to be made between FTA and ETA in order to provide a method which employs deductive logic with a graphical presentation of results. FTA was chosen over ETA because it is very prospectively focussed, has an almost purely graphical nature and concentrates mainly on failure events. It was further felt that a future study with an exploration of their combined use in a two way prospective and retrospective analysis of key events might be informed by this research and would be very useful.

According to some reviewers, HAZOP has been used in healthcare (Redmill et al., 1999b)(Lyons et al., 2004), although no peer reviewed publications were found in a literature search in November 2005, which is when this decision was made. HAZOP was chosen over SWIFT as a creative method using both inductive and deductive logic with its own 'built-in' hazard identification method and tabular presentation. It has the added potential to link the results from a range of assessment methods into an ongoing hazard management system, which may have usefulness in the complex-systems environment of healthcare.

6.3 Hazard identification

Since the hazard list produced in the previous phase of the research was to be used as the comparative data for the evaluation, this could not be used to inform the formal hazard analyses. However, as neither FTA nor FMEA have their own explicit hazard identification processes, a separate method had to be employed for this purpose. The FMEA and the FTA were therefore both based on the same hazard identification map (Figure 6-8) constructed using a modified Delphi method (Robson, 2002e)(Hasson et al., 2000). In the normal Delphi method, participants contribute either individually or in small groups, providing their ideas on the subject under investigation by responding to a questionnaire. These are then analysed and a further set of questions devised. This process is repeated until 'consensus' is reached. The higher the number of iterations performed, the better the result.

Instead of the usual questionnaire based process, the members were asked to brainstorm using a 'spider diagram' after being briefed on the subject of oxygen therapy and made familiar with the system diagram. The meetings were informal and conducted separately in order to reduce the disruption to normal duties. One full and one partial round were completed, giving most members the opportunity to comment on the full hazard identification. This was then used in conjunction with the system diagram for insertion into the structure of the FMEA and the FTA. The Delphi members included a Consultant Anaesthetist, a

Senior Nurse, a Clinical Risk Manager, an Engineering Design Consultant and a Clinical Technologist.

HAZOP has its own hazard identification method making use of attributes and guidewords, which required a little customization for application to this research.

Two full day HAZOP meetings were held with a similar group of members to the Delphi group; a Consultant Anaesthetist, three Senior Nurses, a Clinical Risk Manager, an Engineering Design Consultant and a Clinical Technologist. The hazard identification and analysis were done together in a continuous process in the normal way of HAZOP.

6.4 The FMEA

6.4.1 *Description of FMEA*

FMEA(McDermott, 1996; Ericson II, 2005c) can be used for a wide variety of applications, including full systems analyses.

The essence of FMEA is to answer four questions:

1. What can fail?
2. How can it fail?
3. How likely is it to fail?
4. What will happen if it does fail?

The answers to these are entered into a table linking them all together such as shown in Table 6-2. In the following passage, text in italics indicates column headings.

Table 6-2. An example of an FMEA table.

System	Sub-system	Com-ponent	Failure Mode	Causes	Detection Methods	Effects	Seve-rity	Likeli-hood	Detec-tion	RPN
Oxygen Therapy	1. Supply Equipment	1.1. Piped Supply	1.1.1. No Supply	No gas, Pipeline damaged, Maintenance	Alarm panel	1.1.1a Therapy cannot be set up	6	2	1	12
						1.1.1b Supply fails during use	6	2	1	12
						1.1.1c Change to cylinders	2	2	1	4
						1.1.1d Transfer to another ward	2	2	1	4

The first two questions above are answered qualitatively, with the answer to the first referring to items in a system diagram or process flow chart ('*System*', '*Sub-System*' and '*Component*') and the second describing the manner of failure or '*Failure Mode*'. Although FMEA does not have its own formal method of hazard identification, discussion of these questions with reference to the system diagrams can facilitate hazard identification.

The third and fourth questions are answered both qualitatively and quantitatively. The '*likelihood*' of any '*Failure Mode*' is related to its '*Causes*', which are described and discussed during an analysis. The '*Effects*' of a failure are described and assessed quantitatively by the consideration of their

'*Severity*'. This can often depend on whether or when a failure is detected and the '*Detection*' methods are therefore also first described and then quantitatively assessed.

The '*Likelihood*' and '*Severity*' are scored using scales defined by the assessor. These are often the values normally used in standard risk assessments. The '*Detection*' score is more accurately described as '*the likelihood of failing to detect a hazard or failure mode*' and is usually a number from one to ten. All three need to be defined as precisely as possible before an assessment begins.

The three scores are then multiplied to produce the '*Risk Priority Number (RPN)*'

The table can be extended to include identified preventative or mitigating apparatus, which could be physical barriers or less tangible safeguards such as process interlocks or amended protocols. Further numerical analysis might also be applied to the RPN, such as failure mode or sub-system risk.

6.4.2 *Conducting the FMEA*

The FMEA was conducted by the researcher at Cranfield University following the Delphi hazard identification performed at Bedford and Stoke Mandeville Hospitals. It took place from the beginning of August to the end of December 2007.

The first task was to transfer the hazards from the Delphi map to the FMEA table shown in Appendix E1, Table E.1-1, making direct reference to the system diagram (Figure 4-9). The column headings shown in Figure 6-1 were used in the FMEA with the results from the Delphi map contributing to the first two columns. Each subsystem component ('*System Element*') was taken in turn and the hazards associated with each of them listed as '*Failure modes*'.

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk

Figure 6-1. Column headings of FMEA table.

Next to be considered were the possible '*Causes*' and '*Detection Methods*' of each '*Failure mode*'. These were first listed by the author and then discussed with members of the Delphi group. Where possible, all the feasible causes were included, many of which could occur in combination. A similar approach was used to identify the possible '*Effects*' of each failure mode.

Each '*Effect*' was then risk assessed in three dimensions; '*Severity*', '*Likelihood*' and '*Detection*'. These were then multiplied to give the '*Risk Priority Number*' (RPN). The '*Severity*' and '*Likelihood*' scores were assigned with reference to Table 6-3 and Table 6-4. The score assigned to '*Detection*' indicates the increase to risk from failure to detect the hazard before an incident occurs and was selected by reference to Table 6-5.

Table 6-3. Severity Risk Scores

Severity	Score	Definition
Very Low	1	Distress or inconvenience
Low	2	Minor harm, discomfort or delay
Medium	3	Severe, recoverable harm
High	4	Severe, permanent harm
Very High	5	One death
Extreme	6	Multiple deaths

Table 6-4. Likelihood Risk Scores

Likelihood	Score	Definition
Very Unlikely	1	<1% or < once in 2 years
Unlikely	2	1% - 10% or once in 2 years
Not Very Likely	3	10% - 30% or once a year
Quite Likely	4	30 % - 50% or monthly (12 – 49 per year)
Highly Likely	5	50% - 90% or Weekly (50 – 199 per year)
Almost Certain	6	>90% or Daily (> 200 per year)

Table 6-5. Detection Risk Scores

Detection	Score	Definition
Certain	1	Failure will always be detected
High	2	Failure will be detected approximately 8/10 times
Moderate	5	Failure will be detected approximately 5/10 times
Unlikely	8	Failure will be detected approximately 2/10 times
Impossible	10	Failure cannot be detected

Additional calculations were made in order to assess whether extrapolation provides any added value compared to the RPN on its own.

The RPN was divided by the highest possible score for each effect (360) to give a '*proportional risk*' value. These values were added together to give the '*Total System Risk*'. The proportional risk values of each effect for a particular failure mode were added together and divided by the '*Total System Risk*' to produce a '*Failure Mode Proportional Risk*' relative to the '*Total System Risk*'. These were further appropriately summed to give a '*Subsystem Proportional Risk*' value.

6.5 The Fault Tree Analysis

6.5.1 *Description of FTA*

FTA (Ericson II, 2005c; Tetlow et al. 2005; Boult et al., 2006) is an event driven method in which causes are identified for a '*Top Event*'. These then become events themselves and their causes are identified.

Figure 6-2 shows an example of a Fault Tree and the various symbols commonly used. *Event 1* is the *Top Event* and can only take place if all three the events 2, 3 and 4 also occur. *Event 2* has not yet been further explored while *Event 4* is a normally occurring event and is not a failure or hazard. It does however have a *condition* attached which must be true for it to be considered as *normal*. *Event 3* can happen if either 5 or 6 occur. *Event 5* is a *Basic Event*, one where no further extrapolation is possible or warranted. It is also an *End Event*, which is where the analysis stops. *Event 6* is a type of *End Event* known as a *Transfer Event*, which is part of a Fault Tree that is continued elsewhere (Usually the *Top Event*). There is always a reference indicating where to find this *Transfer (or Sub) Tree*.

FTA, like FMEA, also does not have its own hazard identification method, other than the consideration made when the logic 'AND' or 'OR' gates are applied to each identified *Event*. The nature and propagation of events is considered both before and during the construction of the Fault Tree. This makes it a dynamic method that has to be kept in check to prevent obfuscation due to over analysis and the resultant inclusion of inconsequent information.

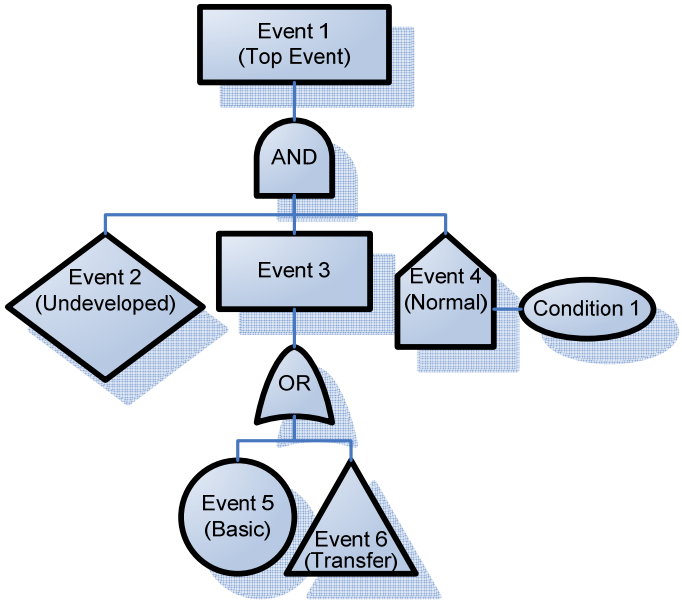

Figure 6-2. An example of a Fault Tree.

The analysis of a Fault Tree results in an expression in Boolean algebra containing the combinations of *End Events* that can produce the *Top Event*. These are called *Cut Sets*. An example using the tree of Figure 6-2 is:

$$Event1 = (Event2 \cdot Event4 \cdot Event5) + (Event2 \cdot Event4 \cdot Event6)$$

Where a dot '·' represents an AND while a '+' represents an OR function.

When these expressions are minimised using normal Boolean logic rules, the result is a collection of the fewest *End Events* which, only when all present, can cause the *Top Event*. The two *Minimised Cut Sets* for the above example are therefore:

$$Event1 = Event2 \cdot Event4 \cdot Event5$$

$$Event1 = Event2 \cdot Event4 \cdot Event6$$

Cut Sets containing only one event indicate that a single hazard can result in a failure or *Top Event* and these are almost always very bad news.

Further analysis can be made if the probabilities of the *End Events* are known. Probability is expressed in values from 0 (impossible) to 1 (certain). Event probabilities combined with ANDs are multiplied and since the values are usually much less than 1, they result in a decreased probability for the event higher up the tree. ORs are added and result in an increased probability for the next event. This process is continued until the probability of the top event has been determined.

6.5.2 *Conducting the FTA*

The FTA was undertaken by the researcher at Cranfield University from the beginning of August to the end of December 2007, following the completion of the Delphi hazard identification conducted at Bedford and Stoke Mandeville Hospitals.

As in the FMEA, transferring the hazards from the Delphi map to the FTA was the first task. This was slightly more complicated with the FTA because the result is not a listing of hazards, but an indication of causality. The *Top Events* (the eventual focal point of an incident) were taken as the failure of each of the system components and the various failure modes and contributory events leading up to this made up the rest of the fault tree. Considering the causal links therefore became the main challenge and most of these were done by a single assessor.

Two versions of the '*Top Tree*' leading to the generic event '*Patient Harmed by Oxygen Therapy System Failure*' were constructed. One was based purely on the system diagram of Figure 4-9, the other on a combination of this and the task analysis of Figure 4-10. To keep the sizes of the trees to a minimum, '*transfer events*' were used to continue analysis in '*sub trees*'. The resulting fault trees are presented in Appendix E2, Figures E.2-1 to E.2-13. Each figure contains a list of minimum cut sets.

Although probabilistic analysis is one of the strengths of FTA, too many of the probabilities were unknown and found to be impossible to estimate. The probabilistic analysis was therefore excluded from all the trees due to a lack of data.

6.6 The HAZOP

6.6.1 *Description of HAZOP*

HAZOP (Redmill et al., 1999b; Ericson II, 2005c) is best described as a very structured, mainly qualitative method with integrated hazard identification and analysis functions.

The HAZOP process starts long before any meetings and the preparation involves a fair amount of work for the lead assessor. The system has to be defined and representations drawn. A team has to be assembled and prepared by training and system familiarization where necessary. The team members need to be focussed on the HAZOP and distraction kept to a minimum, making the choice of venue and meeting planning very important.

The facilitation of a well structured HAZOP requires that the system be defined to the smallest element for inclusion. These elements have characteristic *attributes* which play a vital part in the analysis process. (Gas in storage for example, has volume, pressure, temperature and composition.) Relationships between elements can also be assessed. These might be defined separately in a system representation, which is the normal way, or as part of the attributes for related items.

The single most important part of a HAZOP is the identification of reasons for '*Deviation from Operational Intent*', further referred to in this document as '*Deviation*'. This is achieved by systematically applying Pre-defined adjective '*Guidewords*' such as *'high', 'low', 'less' or 'more'* to each '*Attribute*' of all the elements within a system. These combinations are then explored and any possible hazards or deviations noted.

If possible, a HAZOP leader should make a first pass attempt at the HAZOP and produce a set of worksheets containing this assessment. Figure 6-3 describes the process carried out at each HAZOP meeting. This will usually involve repeating the assessment made by the leader but includes consideration of all the attributes and guideword combinations.

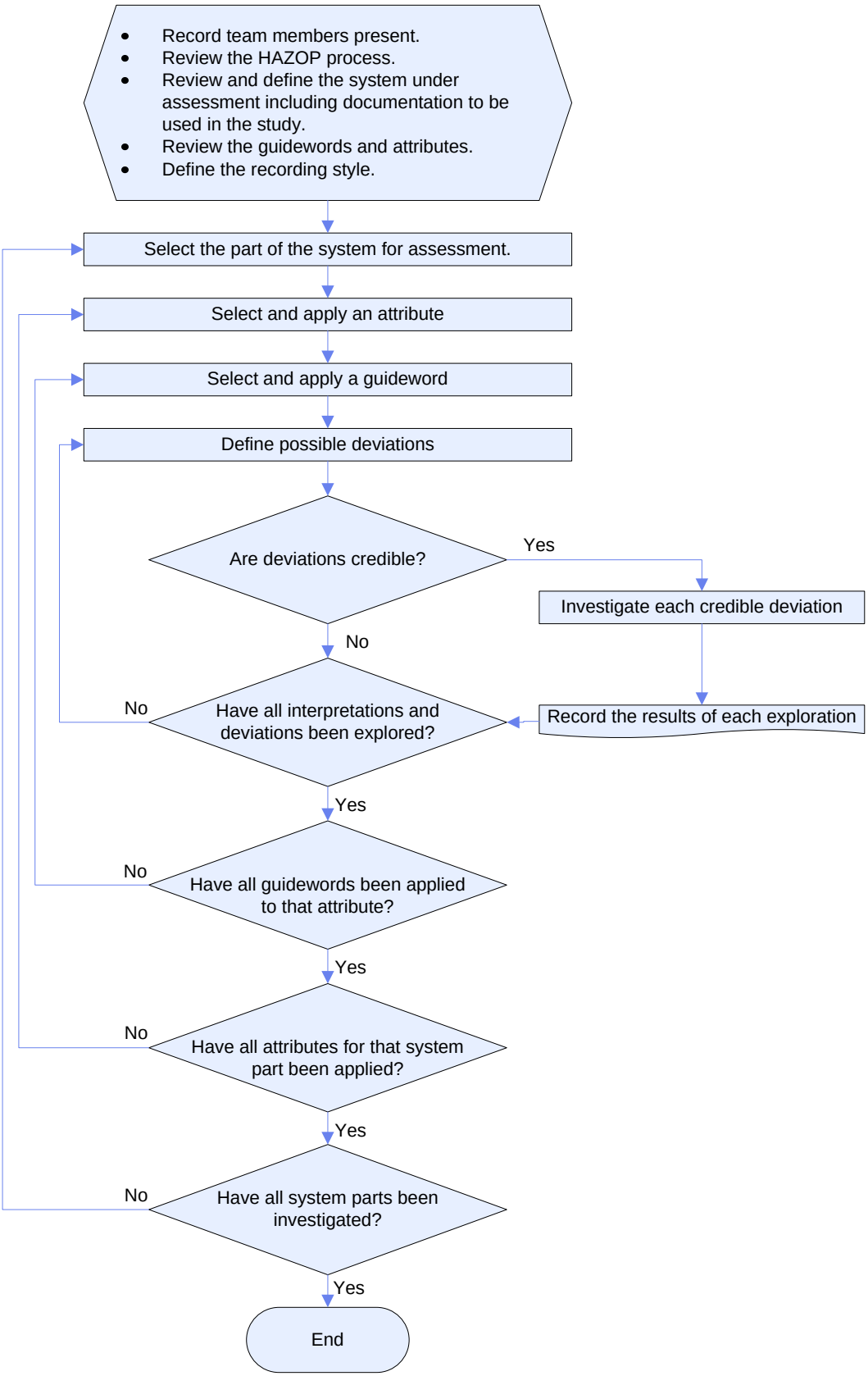

Figure 6-3. The HAZOP Process flowchart. Adapted from (Redmill et al., 1999b)

The results are recorded in a table similar to the example shown in Figure 6-4, in which the first four columns contain the results of the hazard identification. The causes and consequences are then discussed and recorded, which may include a risk assessment. Recommendations for safeguards are then made, or those existing are listed. Any actions that might need to be taken to either install or maintain these safeguards are then noted and might include references to planning or design details.

HAZOP Worksheet

Sheet ID / Date		
System / Subsystem		

Entity	Attribute	Guideword	Deviation	Cause	Consequence	Safeguards	Actions

Figure 6-4. Example of a HAZOP worksheet.

6.6.2 *Preparing the HAZOP*

The system diagram and process flow chart had already been drawn, but the attributes attached to the system elements needed to be established and a series of guidewords defined.

To aid in establishing the attributes, the system parameters listed and defined in Table 6-6 were devised. These were developed from the knowledge gained from the empirical research and by reference to standards (DH Estates and Facilities Directorate 2006) and previous research(Nicola Cooper, 2004; Small et al., 1992; Attia et al., 2004; Fulmer et al., 1984; Bazuaye et al., 1992). Various texts were referred to when considering the human elements of the system. Reason (Reason, 1999a) describes many human interface models and factors that affect cognition when performing tasks. Cacciabue (Cacciabue, 2004) discusses the application and retrospective analysis of human factors theory to safety critical system design and Strauch (Strauch, 2006) expands on some of the human factors issues with specific relevance to complex systems.

Table 6-6. System Parameters and definitions.

System Parameter	Definition
Generic	General factors affecting all parts of the system.
Task	Mainly human factors affecting the way tasks are performed.
Diagnosis	Factors specific to the clinical diagnosis function of the '*Clinical Staff*' system component.
Treatment	Factors specific to the clinical treatment function of the '*Clinical Staff*' system component and the '*Therapeutic Subsystem*'.
Equipment/Accessories	Factors related to the availability of physical system components within the '*Supply Equipment*' and '*Therapeutic*' subsystems.
Assembly	Factors affecting the specific task of assembling the physical components of the system. This is a function of the '*Therapy set-up and monitoring*' component within the '*Clinical Subsystem*' and linked directly to the '*Supply Equipment*' and '*Therapeutic*' subsystems.
Supply	Factors influencing the physical characteristics of the oxygen supply components.
Flow Control	Factors influencing the physical flow of oxygen to and through the '*Therapeutic Subsystem*'
Information	Factors influencing the formulation, storage, movement and use of information.
Communication	Factors affecting the general processes of communication within the system and those outside the system which manifest as external influences.
Physical Environment	Factors such as lighting, temperature or ward design which have an effect on system components and human factors.
Contextual Environment	Factors concerned mainly with the reasons for actions taken and the influence on choices made. E.g. Patient condition, internal politics or external influences
Manual Handling	Factors influencing the way physical components are moved, stored or used which may cause discomfort or injury to staff or patients.

A list of guidewords and their definitions was compiled from some standard listings provided by Redmill (Redmill et al., 1999b) and Ericson (Ericson II, 2005c). These standard examples are applicable to process and timing, but do not have much relevance to placement or position, which could be vital in a healthcare context. The standard list of guidewords was therefore added to so that these issues could be included in a consideration of '*deviation from intent*', which is the basic purpose of a HAZOP. The guidewords and their generic definitions are presented in Table 6-7.

Table 6-7. Generic guidewords and definitions.

No	More	Less	As Well As	Part of	Other than
No part of intent achieved	Quantitative increase is achieved	Quantitative decrease	All design intent achieved with additional results	Some of the intent is achieved	Any result except the intended
Reverse	**Early**	**Late**	**Before**	**After**	**Above**
The opposite result to the intent is achieved or movement backwards	Result achieved sooner than required time	Result achieved after required time	Result achieved too soon in sequence	Result achieved too late in sequence	Position/ Importance relatively higher than
Below	**Behind**	**In Front**	**Through**	**Over**	**Under**
Position/ Importance relatively lower than	Positional posterior or movement to the back	Positional anterior or movement to the front	Positional or movement by way of, piercing or between	Movement higher than. Toppling/falling. Starting again.	Movement lower than or below

6.6.3 *HAZOP Trials*

The HAZOP was conducted at Bedford Hospital following trials at Cranfield University and took place during January 2008.

Trials of the combinations of attributes and guidewords as well as the facilitation of the HAZOP were conducted at Cranfield University with the assistance of a small number of academic and research staff members. The first trial involved the use of a purely electronic method of recording the HAZOP. It soon became evident that this was not viable, as it was too slow to use and there were too many bugs in the software.

Some lessons were learnt about the facilitation of the meeting, particularly that the system boundaries needed to be clearer and that no departure must be allowed from the defined system.

There were further, more serious problems with the system attributes. An attempt had been made to use the system wide parameters as attributes applied directly to each of the system entities. This proved to be too vague and it was almost impossible to define any deviations from the combinations of these parameters and the guidewords. To solve this problem, more specific attributes derived from the system parameters were devised for each system element.

Most attributes were fairly straight forward to identify, but it was slightly more complicated when considering the human factors. For these, the three types of human error identified by Reason (Reason, 1999a) were kept in mind. They are broadly: *Skill based, Rule based and Knowledge based*.

Cacciabue (Cacciabue, 2004) identifies two types of human factors for chemical plants. These are:

- "*Interfaces and Controls*", which includes factors of communication and operation
- "*Context and Environment*", which includes the physical environment and socio-technical factors.

With some minor modification, these also appear suitable for ward based therapies.

Linking these to Reason's three types of human error, the three categories of human factors identified were '*Operation', 'Environment'* and *'Information'*. Table 6-8 shows these categories and their corresponding human factor elements.

Table 6-8. Human Factors (HF) Categories and Elements

HF Category	HF Elements
Operation	Diagnosis, Assembly, Monitoring, Adjustment, Patient Management
Environment	Physical, Knowledge, Skills, Policy, Defined Procedure, Institutional Structure, Management, Hierarchy, Culture, Communication
Information	Gauges, Dials, Indicators, Alarms, Written and Verbal Communication, Examination, Diagnostic Tests

The various human factors attributes were then devised from these and together with the general attributes, assigned to each system component and added to the system diagram (Figure 4-9).

The second HAZOP trial at Cranfield University involved the use of a paper based method, with each panel member having their own copy of a pre-printed worksheet, an example of which is given in Figure 6-5.

The system wide attributes had also been replaced by the more specific attributes applied to each entity which were integrated into the system diagram.

HAZOP Worksheet

Sheet ID		Date	
System		Subsystem	

Entity	Attribute	Guide word	Deviations	Causes	Consequences	Safeguards	Actions	Likelihood (1 – 6)	Severity (1 – 6)

Figure 6-5. The HAZOP worksheet used in the second trial.

This trial was far more successful than the first, with the only real concerns being:

1. The presentation of information during the training and introduction at the beginning of the meetings.
2. The system definitions still needed to be clearer and better presented.
3. The layout and content of the worksheet needed to be slightly amended.

To address these issues:

1. The pre-meeting presentation was amended to have clearer diagrams and the guidewords would be provided to panel members as well as discussed using a projected slide.
2. A more detailed discussion and definition of the system would be provided.
3. Worksheets similar to that shown in Figure 6-6 were constructed which listed each component and attribute along with any guidewords that might be appropriate to each combination. Some deviations were also listed and could be either rejected or ratified during the HAZOP. The '*Causes*' Column was removed and the '*Consequences*' column widened to aid handwritten notes. The '*Safeguards*' and '*Actions*' columns were reduced by making them 'Yes/No' to indicate if safeguards existed or if actions were required.

Entity	Attribute	Guideword	Deviation from intent	Consequences	Likelihood (1 – 6)	Severity (1 – 6)	Safeguards (Y / N)	Actions (Y / N)
1. Piped Oxygen Supply	1. Gas Type	As Well As	1. Correct gas mixed with another substance					
		Part Of	2. Correct gas for some of the time, changing to wrong gas.					
		Other Than	3. Wrong Gas					
	2. Pressure / Supply	No	1. No pressure					
		More	2. Too much pressure					
		Less	3. Not enough pressure					
		Part Of	4. No gas for some time and then gas supply reinstated					

Figure 6-6. An example of the worksheet devised for the first 'live' HAZOP meeting.

6.6.4 *Conducting the HAZOP*

The HAZOP was conducted at Bedford Hospital following the trials at Cranfield University and took place during January 2008. Two full day meetings were arranged and a venue within the participant hospital chosen that was as central and accessible as possible. The conference room chosen had video projection facilities and adequate seating around a circular table.

Both meetings were carefully planned with a clearly laid out agenda. A set of HAZOP worksheets with pre-prepared Attribute/Guideword combinations, system diagrams and definition sheets were also supplied. A presentation to introduce the HAZOP method and define the system was followed by a system familiarisation session before each meeting.

Panel members were asked to fill in their own worksheets and hand them back to the lead assessor at the end of each session. The meetings were video recorded to aid clarification of responses and deciphering handwriting during later transcription of the HAZOP results into a spreadsheet containing the analysis structure.

After the first meeting it became clear that it might have been unwise to completely remove the '*Causes*' column, as this was something that needed to be assessed along with the consequences of a hazard. An attempt was therefore made to generalise the worksheet slightly, as it was felt to be unfeasible to simply add a '*Causes*' column. It was thought that a combined consideration of '*Deviation*', '*Cause*' and '*Consequence*' could be made in one descriptive text field.

It was also clear that almost every hazard could lead to death if the circumstances were right (or wrong). This is an issue reported by DeRosier et al during the development of HFMEA (DeRosier et al., 2002). The range of risk severities were therefore separately assessed for likelihood so that this confusion might be abated.

The resultant new worksheet can be seen in Figure 6-7 and contains new titles for two of the columns. The '*Deviation*' column was changed to an '*Interpretation*' of the combination of '*Attribute*' and '*Guideword*', while the '*Consequences*' column, although simply labelled '*Possible Deviations*', became the combined assessment of '*Deviation*', '*Causes*' and '*Consequences*'. There was also the addition of nested rows for the assessment of likelihood attached to each '*Severity*' rating. These changes were discussed with the panel members and the use of the columns carefully explained before the next meeting.

Transcriptions were made from worksheets handed in by the panel members. Where entries did not agree or could not be deciphered, the video recordings were used to clarify the outcome. The resultant aggregated HAZOP assessments are available in Appendix E, Tables E.3-1 to E.3-4.

After the final session, a short evaluation questionnaire was distributed which asked the following questions:

1. On a scale of 1 to 10, how difficult did you find the HAZOP? (Where 1 is ‘very easy’ and 10 is ‘very difficult’).
2. Would you do it again?
3. Was the use of the printed worksheets helpful?
4. Was it clear from the outset what was expected of you?
5. Was it clear from the outset what was being assessed?
6. Did you feel any progress was being made?
7. Do you think you learnt anything from this exercise?
8. Do you think it was a worthwhile use of your time?

This was intended to assess perceived difficulty, willingness, the usefulness of the worksheets, clarity of expectation, clarity of purpose, progress, learning and value. Further comment was also invited in order to learn of any additional points of concern or useful advice. The results of this survey are discussed later in this chapter.

This evaluation survey method could not be applied to the FMEA or the FTA as they were not conducted by a group; HAZOP is the only one of the methods that cannot be conducted by a single assessor. The survey was not applied to the Delphi process because it was not being assessed as a method in its own right.

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards (Y / N)	Actions (Y / N)
1. Patient	1.1. Age	Above	1.1.1. Over a certain age		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
		Below	1.1.2. Below a certain age		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
	1.2. Condition	More	1.2.1. Condition worse than expected		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
		As Well As	1.2.2. Combined Conditions		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			

Figure 6-7. Example of the worksheet used for the second 'live' HAZOP meeting.

6.7 Notes on the Evaluation

6.7.1 *Evaluation Metrics and Measures*

The hazards identified and assessed by each method were evaluated against the empirical hazard analysis by way of a comparison table (See Appendix E4 Table E4-1). The level of coverage for each hazard was indicated by a symbol in the column representing the particular hazard analysis method, as shown in the key to the comparison table. The results were then examined using basic descriptive statistics and qualitative analysis.

System coverage was qualitatively assessed by examining the subsystems in turn and considering how well they were addressed by each method. A quantitative assessment was made by comparison to the empirical data and assigned a percentage value.

The type and quality of information conveyed and its usefulness to prevention or mitigation of adverse events was qualitatively assessed. Consideration was given to the knowledge gained and how the information related to the system diagram. Judgments were made on whether any use could be made of this information to help prevent the occurrence of incidents or to reduce their consequences.

The difficulties of performing each analysis and the fit within healthcare were also considered and discussed in terms of assembly of teams, format of meetings, time spent out of normal duties and application of the information to practice. Informal discussions with participants regarding the process and presentation of the methods and a short questionnaire in the case of the HAZOP were used for this assessment.

6.7.2 *Limitations*

These analyses refer mainly to the system diagram (Figure 4-9). It would have been more useful to have applied these methods equally to this and the process task analysis diagram (Figure 4-10). Unfortunately, time constraints imposed through the limited availability of group members resulted in the research being more focused on the system diagram. Some specific task related human factors and external influences from institutional errors might therefore have been missed. The Delphi process could also only be completed once and re-assessed by some of the group for the same reasons, providing less than optimal reliability.

The HAZOP had to be completed in two full day meetings, making them long and tedious, increasing the possibility of error due to fading interest and concentration levels. All the methods were thus affected by similar factors, making it possible that they might, to some extent, cancel each other out.

The evaluations were made on a ‘first pass’ analysis from these methods. (That is, only one attempt at an assessment was made). Normal practice would be to perform a number of iterations until all panel members were satisfied with the result or time ran out.

The identification of hazards for the FMEA and FTA is not a function of the analysis method, but more of a reflection on the modified Delphi method. It is therefore not fair to place too much on this when assessing the validity of the hazard analysis method, except for its ability to process the hazards presented in the map. This does however present the opportunity to discuss the differences between a convened group and a dispersed group approach and provides some information on the validity of the method integrated within HAZOP.

6.7.3 *Expectations*

FMEA was expected to perform well in general, but there were some reservations about its inability to handle multiple cause failures (Marx and Slonim, 2003).

It was thought that FTA would give a clear indication of hazard combinations and cascade failures (where one event triggers the next). An evaluation of its probabilistic analysis capability was felt to be impractical at this stage as such data could not be sourced.

Neither of these methods have their own integral hazard identification technique, but it was expected that a modified version of the Delphi method could be used as a means of initial identification. The hazards identified in this way would then be fairly easily transferred to the analysis structures of each method.

HAZOP was thought likely to provide a useful example of a method with its own hazard identification process. Its differences to FMEA and how it could be combined with other techniques were expected to become evident during the comparison of the three methods.

6.8 Results and Discussion

Much of the discussion on the comparison between the analysis methods refers to the table of Appendix E4, Table E.4-1. This table contains the hazard list resulting from the empirical studies, alongside symbols indicating the level of identification attained by each hazard analysis method against each of the hazards. A check mark (✓) indicates complete identification, a tilde (~) indicates partial identification while a cross (X) indicates that the hazard was not identified. The summary of the comparison results is shown in Table 6-9 which is also referred to in the following section.

Table 6-9. Summary of Comparison Results

		Delphi	FMEA	FTA	HAZOP
Fully identified	✓	45	58	58	28
		24%	31%	31%	15%
Partly identified	~	61	55	54	25
		33%	30%	29%	13%
Not identified	X	80	73	74	133
		43%	39%	40%	72%
Total Hazards		186	186	186	186

6.8.1 *Hazard Identification using the Delphi Method*

Figure 6-8 shows the hazard identification map resulting from the Delphi method process. The brainstorming approach to this method seems to have been effective and the participants engaged well with the process. However, the time that the participants could be available for this study had a limiting effect on the breadth and detail of the hazard identifications. This is evidenced by the fact that only 57% of the hazards in the empirical list were identified. (24% full, 33% partial).

Very few external influences were included in the Delphi map and no environmental issues were identified. The few organizational hazards identified were quite general and no institutional factors were included.

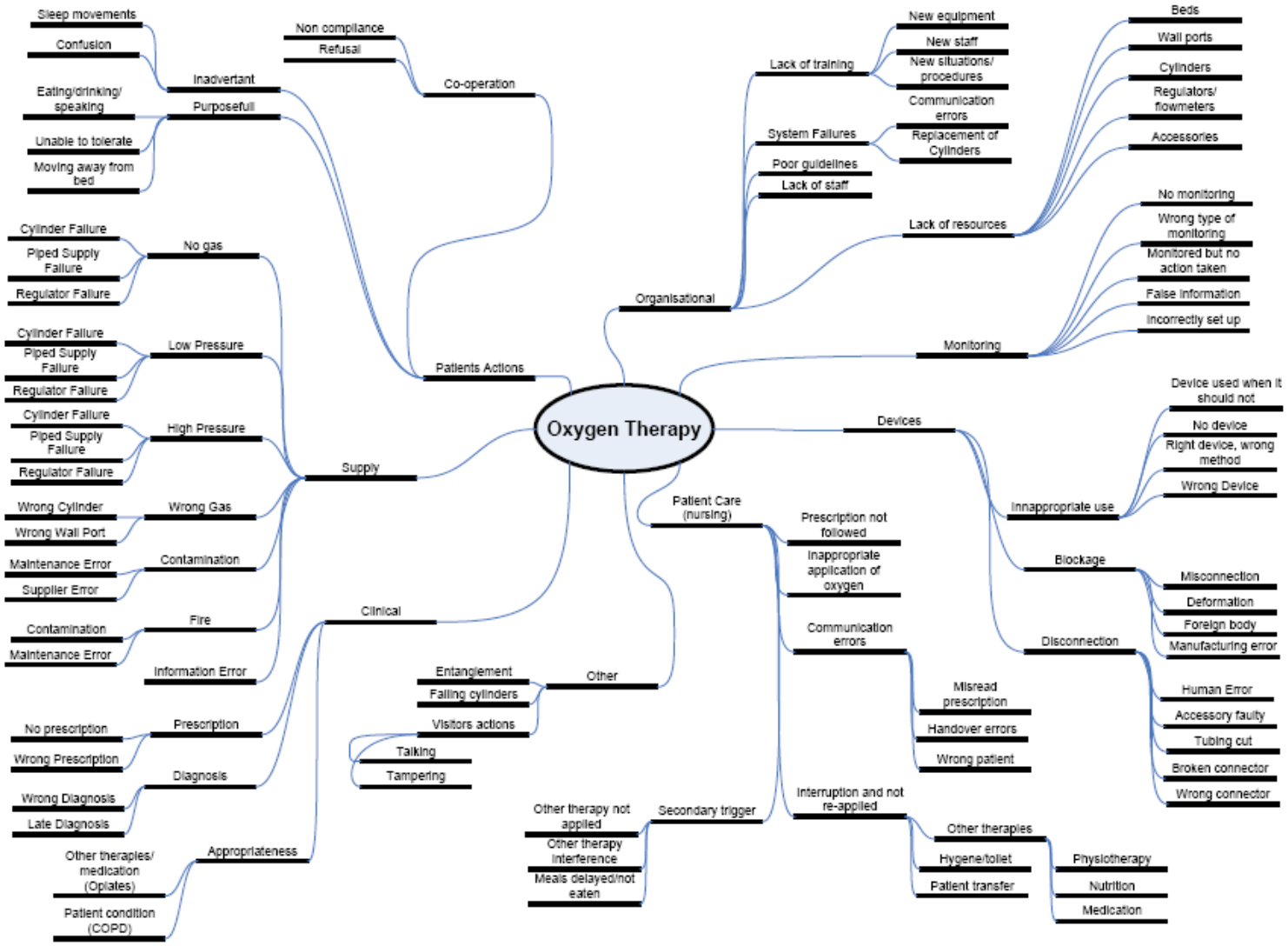

Figure 6-8. Oxygen Therapy Hazard Identification.

6.8.2 *FMEA*

The full FMEA is shown in Appendix E1, Table E.1-1.

Transferring the hazards from the Delphi map took longer than expected, but was relatively straight forward. The most difficult part was relating the hazards to the system diagram and process flow chart. It was easier to map issues to the system diagram than to the process flow chart, although some hazards seemed to have a degree of commonality, especially within the 'Clinical Subsystem'. There may be merit in the procedure adopted in most industries, where separate FMEAs are conducted for system and task or process assessments. These could then be compared and common causes would become evident. It may be that some hazard omissions were made because of the attempt to consider the two domains together.

The comparison results in Table 6-9 indicate that 31% of the 186 empirically identified hazards were covered by the FMEA and that a further 30% were partially addressed. This suggests that approximately 61% of the system was covered to some degree. Organizational, external and environmental issues were not well addressed; possibly because they were not well identified in the Delphi map.

The extended risk analysis attached to the FMEA was compared to the use of the Risk Priority Number (RPN) on its own. As shown in Table 6-10, there was no difference over the ranking of the first twenty failure modes. The risk analysis was based heavily on the expert opinions of the Delphi group members consulted. When compared to the risk analysis contained in the aggregated hazard list of table D.5-1 in Appendix D5, the general themes of '*Staff Availability/Knowledge/Skill*' followed by '*Communication/Information Errors'*, '*Undetected Therapy Termination/Monitoring Errors'*, '*Patient Actions/Co-operation'* and '*Cylinder Management Errors'*, correspond well with those listed in Table 6-10.

The clear, compartmentalised nature of the tabular layout of FMEA creates a tendency towards unitary thinking, where only one failure mode and effect combination is considered at a time. Although this is a limitation in terms of common causes, it makes it easier to estimate severity, likelihood and detection scores. The highly structured layout also lends itself to the analysis of hazards per sub-system or system element and can be mapped directly to the system diagrams. It is easily constructed in any spreadsheet or even word processing software and fits in well with the use of 'brainstorming' for the identification of hazards.

Table 6-10. Extended Risk analysis Compared to Risk Priority Number.

Failure Mode	Proportional Risk Scores	Failure Mode	RPN per Failure Mode
3.4.2. Over tasked	0.0676	3.4.2. Over tasked	720
3.3.3. Therapy status not monitored	0.0451	3.3.3. Therapy status not monitored	480
3.4.1. Staff not available	0.0399	3.4.1. Staff not available	425
2.6.7. Moved into inappropriate Position / Placement	0.0338	2.6.7. Moved into inappropriate Position / Placement	360
3.4.3. Fail to communicate	0.0263	3.4.3. Fail to communicate	280
1.3.5. Pressure gauge reading High	0.0188	1.3.5. Pressure gauge reading High	200
3.1.2. Does not co-operate	0.0188	3.1.2. Does not co-operate	200
3.4.4. Insufficient knowledge / Skill	0.0188	3.4.4. Insufficient knowledge / Skill	200
3.4.6. Therapeutic requirement error	0.0188	3.4.6. Therapeutic requirement error	200
2.1.5. Incorrect Information	0.0178	2.1.5. Incorrect Information	190
1.2.2. Empty	0.0177	1.2.2. Empty	188
1.4.7. Flow Reading Low	0.0169	1.4.7. Flow Reading Low	180
2.3.3. Tubing too long	0.0169	2.3.3. Tubing too long	180
2.1.4. No Information for Decision	0.0160	2.1.4. No Information for Decision	170
1.3.6. Leaking	0.0150	1.3.6. Leaking	160
3.1.4. Moves or removes mask	0.0150	3.1.4. Moves or removes mask	160
3.2.2. Use error	0.0150	3.2.2. Use error	160
2.3.6. Connections loose	0.0141	2.3.6. Connections loose	150
3.2.4. Incorrect information	0.0141	3.2.4. Incorrect information	150

6.8.3 *FTA*

Translating hazards from the Delphi map to the FTA was found to be more difficult than for the FMEA. This was thought to be due to two factors:

Firstly, the hazards contained in the Delphi map had to be translated into events. It became evident that many of the hazards could be linked to more than one type of event and that there were instances where hazards had to combine to form an event. In some cases, non-hazardous events had to be included as conditional elements, such as '*Non re-breathing mask used*' in the '*Applied Part Displaced*' tree. Secondly, consideration of the causal links had to be made carefully and took longer than expected. It did however allow for further exploration of hazardous events, expanding on the basic descriptions as the trees took shape.

The comparison with the empirically derived hazard list shows that 31% of the 186 hazards were addressed by the FTA while 29% were partially covered, resulting in a system coverage of approximately 60%. This compares very closely with the FMEA and the Delphi method, which might appear unremarkable.

There were many startling omissions, even when compared against the Delphi map. This was very surprising when one considers that the Delphi map was used as the main hazard identification method. Some of these were due to the FTA being incomplete (tubing errors for example). Others such as Appendix D5,

Table D.5-1, hazard 14; '*Administering or adjusting another therapy causes interference with this one*', would seem to have just 'slipped through the net'. It may be that, as with the FMEA, an iterative process with more than one assessor would have corrected such omissions.

There was a lack of temporal consideration in some areas, such as whether diagnoses were timely, or if the therapy was applied soon enough. These were issues not covered by the FTA even though it should be possible to do so.

Risk analysis was not assessed as the probabilistic functions of FTA could not be used due to a lack of data. It may have been feasible to attach some standard likelihood assessments to the trees, but access to experts to carry this out was not possible.

Hazards and causal links are easily identified from the trees and this aids in the identification of safeguards and barriers. A means of drawing the trees and a proficient assessor is required to both construct and explain them to someone seeing them for the first time.

6.8.4 *HAZOP*

Arranging the two full day meetings proved to be very difficult. Most healthcare professionals have very busy schedules and the HAZOP was only made possible through a key gatekeeper. These meetings were too long and this may have contributed to omissions due to tiredness.

Facilitating the meetings was also a challenge, mostly due to the fact that HAZOP has a format that is quite alien to those who have experience in other less formal methods. This was compounded by the difficulties experienced in the risk assessment and the subsequent amendment of the worksheets. This was an ill advised change and damaged the validity of the study by causing confusion over the purpose and distinction of the 'Interpretation' and 'Deviations' columns. The risk assessment was also substantially different in the second meeting and meant that this could not be meaningfully assessed by comparison to those made within the empirical list and the FMEA.

Fewer hazards were identified than during the FMEA or the FTA. Only 15% of the 186 empirically identified hazards were covered by the HAZOP and 13% were additionally partly included. This makes for only 27% system coverage. This has to be taken somewhat in context as the HAZOP could not cover the whole system in the time available.

It is evident that HAZOP has the potential to identify not only failures and hazards, but also exacerbating issues. During the second meeting, a long discussion resulted from an attempt to clarify how a lack of communication between a patient and a clinician might be hazardous to the patient's safety. All the panel members felt that there had to be some identifiable hazard, but it was elusive. This would seem to be due to there being no direct hazard, but that such a situation might cause a normally simple problem (like a matter of comfort for example) to become far more likely to escalate into an incident. Most hazards of this sort require some kind of conditional state to exist and this is where HAZOP seems to struggle.

It was surprising how, even though certain general topics had been discussed, some hazards were hard to pin down. For example, patient and therapy monitoring was discussed as part of many of the hazards, yet it was not assessed in itself. It may be that it would have been covered later when the therapy set-up was assessed. It is also an element in the '*Clinical Subsystem*' and as such would have been assessed had time permitted. There is also a suggestion of common causes produced from the repeated discussion of this subject at different times in the analysis, but this is an area where HAZOP struggles.

The fact that it was not possible to perform a full system HAZOP was taken into account during the assessment by conducting a second analysis considering only those parts of the system included in the two HAZOP meetings. The identifications are summarised as percentages of the remaining 112 hazards as in Table 6-11. This indicates that the HAZOP still lagged behind the other methods slightly, with a 44.6% system coverage compared to 56.3% by the FTA, 61.6% by the FMEA and 63.4% by the Delphi method.

Table 6-11 Percentage Hazard Identifications adjusted to HAZOP coverage

	Delphi	FMEA	FTA	HAZOP
Fully Identified	32.1%	29.5%	28.6%	24.1%
Partly Identified	31.3%	32.1%	27.7%	20.5%
Not Identified	35.7%	37.5%	42.9%	54.5%

Using this same data, the correlation matrix of Table 6-12 suggests that HAZOP had a rather weak correlation with the other methods, although it did seem to agree slightly better with the FTA and FMEA than with the Delphi.

Table 6-12. Correlation between HAZOP and the other methods

	Delphi	*FMEA*	*FTA*
FMEA	0.56		
FTA	0.54	0.71	
HAZOP	0.19	0.37	0.35

The results of the evaluation questionnaire are summarised in Table 6-13below.

Table 6-13. Results of the HAZOP Evaluation Questionnaire.

		Totals				
Question	Theme	Ave	y		n	
1	Difficulty (1 to 10)	5.2				
2	Willingness		5	100%	0	0%
3	Worksheets		5	100%	0	0%
4	Expectation		4	80%	1	20%
5	Subject		3	60%	1	20%
6	Progress		5	100%	0	0%
7	Learning		5	100%	0	0%
8	Value		4	80%	0	0%

Comments received were: "*It has given me knowledge of HAZOP*", "*Too long*" and "*Interesting and thought provoking*".

6.8.5 *General Points*

A comparison of the hazard identification method within HAZOP and that of the Delphi method to the empirical research reveals that although some hazards identified in the empirical research were not explicitly identified by either the HAZOP or the Delphi method, there was some implicit inclusion. For example, '*Latent error in procedure causes mistakes*' identified in the empirical research may be a cause of '*Wrong patient*', which was identified in the Delphi map.

In 18 cases, even though the Delphi map did not contain a reference to a particular hazard, it was identified by either FMEA or FTA. The analysis presented in Table 6-14 shows the correlation coefficient between the Delphi map and the FMEA to be very similar to that of the Delphi map and FTA, but that between the FMEA and FTA it is slightly stronger.

Table 6-14. Correlations between Delphi, FMEA and FTA.

	Delphi	*FMEA*
FMEA	0.49	
FTA	0.45	0.66

Although the empirically derived hazard list was distilled twice, when the comparison with the hazard analysis methods was made, it was discovered that there were still two hazard descriptions that were essentially the same as another two. It should be pointed out however that the empirical list may have contained very similar hazards in more than one subsystem. This is something also evident in the FMEA as well as in the FTA where entire sub-trees are duplicated.

There was no clearly identifiable pattern to the hazards identified in the empirical list but not in the formal hazard analyses, other than that many were task related. This was possibly due to the focus placed on the system diagram as the main source of reference. Some other issues missed were those that were indirect, such as '*Incorrect actions at patient handover'*. There were only 38(20%) hazards missed by all three formal methods and these are listed in Table 6-15. This low number and their mainly task related nature suggests that a combinational approach is effective in capturing at least 80% of the hazards identified through empirical research. This would satisfy a Pareto analysis.

Table 6-15. Hazards missed by Delphi, FMEA, FTA and HAZOP.

Subsystem	Component	Hazard ID	Hazard Type
Clinical	Staff	8	Patient management errors when patients arrive after transfer
Clinical	Staff	21	Patient requests or needs unfulfilled
Clinical	External - Environment	27	Environmental factors such as noise masking calls for assistance
Clinical	External - Environment	33	Surplus equipment cluttering the ward area
Clinical	Therapy Setup	36	Equipment improperly checked
All	All	38	Technical or physical failures of the bed or associated equipment
Clinical	Therapy Monitoring	40	Failure to respond to an equipment alarm or warning
Clinical	Patient/Patient Monitoring	47	Patient actions adversely affecting patient monitoring
Clinical	External - Environment	51	Environmental factor obscuring a clear view of the patient
Clinical	External - Environment	52	Environmental factor obstructing access to the patient
Clinical	Staff/Patient	55	Changing a patients posture or position interferes with the therapy
Clinical	Staff/Patient	57	Moving a patient between bed and chair causes interference with the therapy
Clinical	Staff	59	Incorrect actions at patient handover
Clinical	Therapy Setup	60	Incorrect actions during patient transfer
Clinical	Patient	64	Equipment delivering another therapy fails causing interference with this one
Clinical	Therapy Setup	105	A factor relating to design within the therapy or the environment causes setup error
Clinical	Therapy Setup	126	Wrong type of accessory used for a particular therapy setup
Clinical	Patient Monitoring	141	Sensitive alarms and persistent nurse calls from patients
All	External - Infrastructure	146	Lifts are shared with all building users
Clinical	Patient	153	Smoking
Clinical	Staff/Therapy Setup	154	Delayed Action from Staff

Subsystem	Component	Hazard ID	Hazard Type
Clinical	External - Other Therapy	159	CPAP/BIPAP Problems
All	External - Person	162	Actions of Paediatric Patient's Parents
Supply	Piped	166	Collision between patient and pipeline outlet hardware
Clinical	Staff	167	Communication/Structure - refusal to assess patient
Clinical	Staff/Therapy Setup	169	Contamination hazard - Used accessories not disposed of and replaced
Clinical	Staff/Cylinder	173	Cylinder management error - Not turned off after use
Clinical	Staff/Therapy Setup	176	Distraction of staff - Issue with this therapy puts other patients at risk
Clinical	Staff/Therapy Setup	183	Equipment not checked
Clinical	Patient/External - Person	188	Inappropriate advice to patient from unauthorized person
Therapeutic	Tubing	189	Infection risk - Fungus in oxygen tubing
Clinical	External - Infrastructure	190	Infrastructure - Emergency buzzer inaccessible
Clinical	Patient Monitoring	194	Monitoring equipment - Physical harm from sensors
Clinical	Staff/Patient	200	Patient left unattended
Clinical	Staff/External - Person	203	Procedural error - Delegating clinical/nursing tasks to parents
Clinical	Staff/Cylinder	209	Staff knowledge/Skill - not able to identify an oxygen failure alarm
Clinical	Staff	211	Transferring without adequate escort
Clinical	Staff/Therapeutic Subsystem	215	Unsuitable running repairs

6.9 Conclusions

In this chapter, the combined results from the empirical research studies in the form of a list containing 186 hazards was used to assess the applicability of Failure Modes and Affects Analysis, Fault Tree Analysis and HAZOP to ward based healthcare. The number and type of hazards, level of system coverage and presentation of results were considered and discussed, as were the techniques of risk assessment and the general ‘usability’ of the methods.

The following subsections contain a synopsis of the main points raised.

6.9.1 *FMEA*

Although transferring the hazards from the Delphi map to the FMEA was fairly uncomplicated, it was easier to relate the FMEA structure to the system diagram than the process flow chart.

Table 6-9 indicates that approximately 61% system coverage was achieved. Organizational and environment issues were not well addressed, which might have been a legacy from the Delphi hazard identification.

FMEA provides a useful opportunity for a very detailed risk analysis that has direct linkage with both hazards and system elements. This makes ranking of requirements for safeguards and barriers very much simplified. The comparison with the risk analysis based on the empirical research suggests that expert opinion is a valid source of information for the assessment of risks. It is helpful to be able to rank the system elements and sub-systems in terms of risk, but, as implied by the comparison with the extended analysis, this can be done through some simple arithmetic using the RPN.

The firm, clear structure of FMEA aids in focusing attention on the risk assessments and the analysis of individual hazards. It also makes mapping of the hazards to the system diagram or process flow chart easier, each of which should rather be done separately than trying to combine them.

The strongly formal, refined structure of both the HAZOP and Delphi methods makes duplication much less likely. Some duplication did still occur in both the FMEA and FTA. This shows common causality, something the HAZOP is not very good at, perhaps because of the highly rigid structure.

6.9.2 *FTA*

Some difficulty was encountered when translating hazards from the Delphi map into events. Therefore, although ‘brainstorming’ can be used for hazard identification, it is not necessarily straight forward to translate hazards or themes into events. FTA provides the vital causal linkage information that methods like FMEA are not capable of, as they focus on individual failures and hazards, rather than the interplay of events.

A similar proportion of the system (60%) was covered by FTA compared with FMEA. A statistical analysis shows however that they only have a moderate correlation to each other (0.66) and even less to the Delphi map (0.45 with FTA, 0.49 with FMEA). This suggests that they each went further than the Delphi map with some commonality, but also identified different hazards to each other.

It is theoretically possible to produce a risk analysis based on probabilistic calculations, but this is an area where ward based healthcare has a lack of data.

FTA works best with the use of software capable of drawing the logic diagrams. It also requires that the assessor has specific training in the method and is familiar with the use of logic symbols, Boolean algebra and probability. Although

these are not particularly difficult to learn, some time is likely required before an assessor can be considered proficient in this method.

6.9.3 *HAZOP*

The HAZOP required the most modification and preparation out of the three methods. It was also the only one that required that all members of the panel were present at the same time.

A combination of the time constraints and the fact that the hazard identification and analysis tasks are done together meant that the HAZOP only achieved system coverage of approximately 44.6% even when a large part of the system is excluded from the consideration. Only 27% was achieved if the entire system is included. This is not necessarily an indication of failure, but of possible specificity. More time and further iterations combined with higher levels of familiarity with the process of HAZOP by the panel members would possibly have yielded better results.

Complications caused mainly by the changes introduced after the first HAZOP meeting meant that the risk analysis part of the study could not be fully assessed. The only conclusion possible to draw is that the process of assessing the likelihood of all categories of consequence for every deviation is much easier to achieve than a single generalised assessment of each one.

The evaluation questionnaire indicated that the participants were willing, thought the worksheets were helpful, that progress was clear and that they had learnt from the process. Most participants (80%) knew what was expected from them but fewer (60%) were clear about what was being assessed. Difficulty was rated as ‘moderate’ (5.2/10). General comments indicated that the meetings were too long but that the process produced learning in the subject under review, HAZOP itself and the concept of prospective analysis and action.

6.9.4 *General*

It was generally found that formal Prospective Hazard Analysis (PHA) presented added value through:

- Detailed, relevant and reliable information for system modification for the purposes of safety and quality improvement.
- Valid, accurate risk assessment, especially if based on a combination of expert opinion and empirical data.
- The provision of a mechanism for evidence based identification of hazard barriers and safeguards.
- The provision of a method for formal communication of results at any stage of an analysis.
- The provision of a vehicle for documented learning through prospective analysis incorporating feedback from previous experience and adverse incidents.

It would seem that each method had both merit and disadvantage in this context. FTA and FMEA both had better system coverage than the HAZOP and

identified more hazards than were contained in the Delphi map, which was used as the initial hazard identification method common to both techniques. FMEA and HAZOP needed some modification before use, with HAZOP requiring the most extensive adjustment. FTA was the only method capable of displaying causal linkage, but required that hazards be translated into events for analysis. It has a very useful graphical presentation which does however require a user to be familiar with logic symbols and Boolean algebra.

Many errors of omission were made in transferring the hazards from the Delphi map to the FMEA and the FTA while simultaneously linking them to the system diagram and the process flow chart. Time pressure played a part in this, along with the fact that the transfer was made by a single assessor. It is possible that many of these omissions would be rectified by a more iterative process and at least one more assessor to provide verification.

It was not possible to apply probabilistic analysis to the FTA due to a lack of data. This could be rectified in practice by constructing a fault tree based on an FMEA or a HAZOP. The latter methods would provide the probabilistic data and a solid structure, while the FTA makes it possible to examine causal linkages; something the tabular methods cannot accomplish. This is a practice advocated by Ericson (Ericson II, 2005c).

There were many cases where it could be seen how each analysis method might have taken account of hazards identified in the empirical research when these were not included in the formal analyses. The formal methods in combination identified 80% of the hazards compared to the empirical list and many of those omitted may well have been identified through a task based analysis. It is not too much conjecture to believe that a more thorough hazard identification process and additional time may have aided in the inclusion of many of these for assessment. This also supports the idea of combining formal methods to ensure a reliable result.

The two most striking conclusions are therefore that:

1. The use of these methods requires that systems and processes are clearly defined and presented. This provides a valuable opportunity for learning and the capture of tacit knowledge in itself.
2. These methods each have different advantages that can be combined as a structured means for the enduring capture and dissemination of knowledge on hazards and risk that can be continually updated and used for the formulation of strategies for safety and quality improvement.

Chapter 7 Conclusion and Discussion

7.1 Introduction

The objective of this research was to evaluate a small number of hazard analysis methods applied to a ward based therapy in order to assess the contribution they might make to patient safety.

In the introduction to this thesis, a hypothesis was formed based on the research question:

> *'What is the contribution that formal hazard analysis can make to the assessment of patient safety within ward based therapies?'*

It was hypothesized that a number of hazard analyses based on a common frame of reference, using formal methods, would produce comparable, value-added results when tested against empirical research.

The following aims were identified from this:

1. To construct a comprehensive hazard list and risk assessment of a ward based therapy using empirical research.
2. To conduct a small number of structured hazard analyses using different formal methods, each based on a common frame of reference built from empirical research.
3. To evaluate the suitability, advantages and disadvantages of structured hazard analysis methods to the context of ward based care by comparing the formal hazard analyses to the results from empirical research.

These aims were met through the application of a three phase research strategy that involved:

1. The construction of a hazard list compiled from the results of three empirical studies was described in Chapters Four and Five and is available in Appendix D5. As well as this, the production of a system diagram (Figure 4-9) and process flow chart (Figure 4-10) were also achieved.
2. Conducting formal hazard analyses using Failure Modes and Effects Analysis, Fault Tree Analysis and Hazard and Operability Analysis.
3. Comparing these methods to each other and to the resulting hazard list produced from the empirical research in phase one.

Each section of the thesis will now be discussed and conclusions drawn about whether these aims and objective have been met and how the chapters contributed to the research.

7.2 Background

Chapter one introduced the research and described the background to the project. The scope of the research was defined and the research and thesis structures were outlined. The two ways in which this research contributes to current knowledge were described as:

1. The apparent lack of techniques available for assessing hazards inherent in ward based therapies was addressed by testing three established methods by application to oxygen therapy. These formal hazard analysis methods were evaluated, taking account of the difficulty and value-added contribution of each by comparison to each other and to a specially constructed hazard list.
2. The trials and comparisons further provided the first known comprehensive analysis of the hazards and risks associated with the administration of oxygen therapy.

7.3 Literature Review

The themes of; '*Patient Safety', 'Hazard Analysis', 'Oxygen Therapy'* and '*Complexity'* were explored and discussed in chapter two. The history of patient safety, focusing mainly on the United Kingdom, was examined (Hoyle, 2005; Vincent, 2006b). It was concluded that although much has been achieved, there is still more to do in the area of ward based care, where many reported incidents have their origin (Nguyen et al., 2001b).

The large number of hazard analysis methods used in many areas of endeavour creates something of a dilemma for those with a need to apply such techniques to healthcare (Lyons et al., 2004). Some work has been done to aid the choice for general task analysis and human factors, but little has been published concerning the validation or appraisal of these methods to ward based care (Kirwan, 1996). Seven methods; FMEA, FTA, ETA, HAZOP, SWIFT, HEART and THERP, were considered for evaluation in this research and generally described.

Oxygen therapy has received some interest from a variety of angles, including the physiological effects (Benditt, 2000; Fisher, 1980) and some specific issues with methods of delivery or patient monitoring (Attia et al., 2004; Akbar and Campbell, 2006). Very little could be found in published literature regarding the overall consideration of the hazards of oxygen therapy and those that were found (Small et al., 1992; Fulmer et al., 1984; Martin, 1999) did not include the use of structured hazard analysis.

Many ward based therapies are in themselves complex in nature and all are part of the wider system of healthcare, which is undoubtedly so. It was therefore felt relevant to include elements of the science of complexity in order to comment on and take consideration of this characteristic. It was discovered that six principles have been identified (Webb, 2006; Stacey, 2003) and these were applied to ward based healthcare to aid in describing the system and the process of oxygen therapy.

Chapter three discussed the methodology, explaining the 'Pragmatist' philosophy and how it was adopted for this research. The various empirical methods available were considered and their selection for use in this research was discussed. The early expectations of results were also briefly discussed as were solutions to the initially anticipated problems.

7.4 The Empirical Research

Three empirical studies were conducted with the common aim of producing a comprehensive, validated hazard list and associated risk analysis. First, following ethical approval and permission from the hospitals concerned, observational research was carried out at two sites. Immediately after these observations, questionnaires were distributed to a range of healthcare professionals asking about their experiences with oxygen therapy. Finally, after negotiating access to nationally reported incidents involving oxygen therapy, 5,755 incident reports were examined and categorised using a specifically designed taxonomy.

The observational research detailed in Chapter four identified 499 events over 25 studies in which 178 subjects were included. 684 analyses were conducted on these events during which categories and sub-categories of hazards were identified and outcomes were considered. The range and variations of administration methods were examined and together with the outcomes analysis and national statistics on hospital episodes was used to gauge the size of the problem in the UK. It was found that simple face masks and nasal cannulae together account for about 70% of the accessories used for oxygen therapy and that approximately 8% of admitted patients (about 1.3 million) receive oxygen each year. If 6% of these patients experience a problem with oxygen therapy, over 80,000 patients may be affected by an adverse incident each year.

Also detailed in Chapter Four, the questionnaire study helped to support and augment the results from the observations. 293 statements were made in response to four open questions, resulting in the identification of 54 hazard themes. It was estimated that approximately six adverse events are experienced by individual professionals per year. By using a proportional risk score for hazard themes, it was shown that there is most concern about the management of patients with Chronic Obstructive Pulmonary Disease (COPD), the problem of cylinder depletions and incorrect dosage levels. Of least concern were the issues of equipment failures and problems with piped supplies.

One question addressed the ranking of hazards by proportional frequency. The results closely agreed with the combined risk estimate from other questions, with the addition of general setup errors, which was also indicated as a prominent source of risk.

The combination of responses to questions about guidelines and the demographic and involvement data indicated a general consensus over the issue of patient safety with oxygen therapy. No particular professional group showed more concern than the others and all were interested in aiding patient safety. Most agreed that guidelines are inadequate on their own and need to be supported through training and communication.

The combined hazard list from these two pieces of research is presented in Appendix C1 Table C1-1. It contains 119 hazards, detailing their hazardous elements, triggering mechanisms and posed threat. A system diagram and process flow chart were also produced from the combined results of these two studies (Figure 4-9 and Figure 4-10).

The third empirical study was discussed in Chapter Five. This pivotal research study was designed partly as a feedback mechanism by which to validate the hazard list produced from the observations and questionnaire. It also had the purpose of identifying further hazards and applying a risk analysis to them from a slightly different perspective. It began by developing a taxonomic categorisation structure and method, which was developed from the results of the observations and the questionnaire and verified over two rigorous trials.

Following the negotiation of a data sharing agreement with the National Patient Safety Agency (NPSA), 5,755 oxygen related incident reports covering England and Wales were made available for this research. Four Consultant Anaesthetists, a Research Associate from the NPSA and a Clinical Technologist reviewed and categorised these reports, listing all possible contributory factors and where possible, stating the context in which each valid incident may have occurred.

The reliability of the resulting categorisation was tested using Krippendorff's Alpha ($K\alpha$) and showed mixed results. A degree of disagreement is however advantageous in the context of hazard identification, as it indicates a variety of views, which was in fact the purpose of having a diverse research group. $K\alpha$ was also used to calculate the probability of an elements' contribution to an incident through an estimation of relevance based on frequency of occurrence and the reliability score. This and an estimate of harm calculated using a weighted scoring method were applied together to produce a risk analysis for each hazardous element in the taxonomy.

The previously constructed hazard list was validated by the high degree of similarity of identified hazards (see Appendix D4). It was also amended, based on the additional identifications made from the incident reports. The final aggregated hazard analysis is presented in Appendix D5, Table D.5-1. A total of 188 hazards were identified through distillation of the combined analyses (later further reduced to 186). The table is arranged by alphabetical listing according to the system diagram (Figure 4-9).

7.5 The Evaluation

The final stage of the research is presented in Chapter Six and is the confluence of the combined empirical research and the formal hazard analyses described in Chapter Six. The objective was to evaluate a small number of prospective hazard analysis methods to gauge their applicability to the analysis of ward based therapies and to assess the added value they might bring to learning for the benefit of patient safety.

First of all, the hazard analysis methods to be evaluated had to be chosen from the large number in current use in industry. The selection process and the final choice of Failure Modes and Effects Analysis (FMEA), Fault Tree Analysis (FTA) and Hazard and Operability Analysis (HAZOP) was described.

It was concluded that each method had both merit and disadvantage in this context. FTA and FMEA provided better system coverage than the HAZOP and identified more hazards than were contained in the Delphi map, which was used as the initial hazard identification method common to both techniques. FMEA

and HAZOP needed some modification before use, with HAZOP requiring the most extensive adjustment. FTA was the only method capable of displaying causal linkage, but required that hazards be translated into events for analysis. It has a very useful graphical presentation which does however require a user to be familiar with logic symbols and Boolean algebra.

It was further concluded that formal Prospective Hazard Analysis (PHA) presented added value through:

- Detailed, relevant and reliable information for system modification for the purposes of safety and quality improvement.
- Valid, accurate risk assessment, especially if based on a combination of expert opinion and empirical data.
- The provision of a mechanism for evidence based identification of hazard barriers and safeguards.
- The provision of a method for formal communication of results at any stage of an analysis.
- The provision of a vehicle for documented learning through prospective analysis incorporating feedback from previous experience and adverse incidents.

Two further striking conclusions were that:

1. The use of these methods required that systems and processes were clearly defined and presented. This provided a valuable opportunity for learning and the capture of tacit knowledge.
2. These methods each have different advantages that might be combined as a structured means for the enduring capture and dissemination of knowledge on hazards and risk that can be continually updated and used for the formulation of strategies for safety and quality improvement.

7.6 Suggested Application and Future Work

Although empirical research can identify hazards and even be used to discover the probabilities and severity of some, a formal structure is still required so that the results can be usefully presented. The empirical research conducted during this project was as comprehensive as possible, but it may be that shorter studies, informed by a prospective preliminary analysis based on HAZOP or FMEA and Pareto analysis, could be used to examine specific issues.

Figure 7-1 outlines a recommended process of hazard management based on the experience gained from this research. The first step would be to define the system under assessment by using system diagrams and process flow charts. A first stage assessment could then be carried out using HAZOP or FMEA, based on the system definition. Any gaps in knowledge should be corrected using empirical research methods such as observations, document review and staff and patient surveys. Once the system definition has been updated using this new knowledge, a second stage assessment can be carried out, with finer detail added (such as causality and probability) using Fault Trees or Event Trees linked to the main hazard analysis. Safeguards and hazard barriers are

identified and developed based on the second stage analysis and put in place. This changes the system and a new description has to be defined. The second stage analysis is then re-visited and the process continued through as much iteration as necessary until no further knowledge gaps exist and no new safeguards or barriers are feasible. The final step is to wait until either the system changes in some way or a time limit is reached, which would each trigger a new assessment.

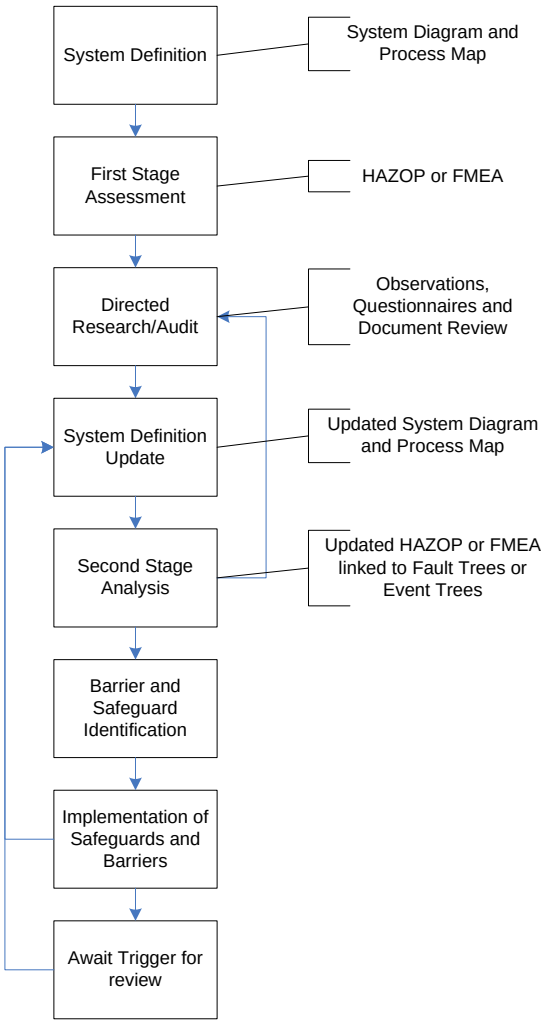

Figure 7-1. The Prospective Hazard Management Process

The main benefit from the use of Prospective Hazard Analysis (PHA) is that it can be used to examine escalations in consequence. For example: If oxygen cylinder depletion is identified before a patient is harmed, the only consequence is a minor disruption in therapy. If detection occurs after a drop in the patient's blood oxygen level, harm has already begun and any further delay could prove fatal. The system can then be modified to include a reliable means of identifying a state of near depletion with the requirement that urgent action is taken at this point rather than when it is already too late.

This research has confirmed what was expected and many commentators have said about the differences in the analysis of hazards and presentation of results obtained from each of these formal hazard analysis methods.(Lyons et al., 2004; Redmill et al., 1999a; Bertolini et al., 2007) FMEA and HAZOP are both very useful for formal hazard identification and analysis of causes. They both therefore lend themselves for use as prospective frameworks for application as a predictive mechanism pre-event as shown in the green section of Figure 7-2. Fault Tree Analysis is also useful as a prospective method and can provide an event driven analysis showing causal linkages such as common causes and cascade events.

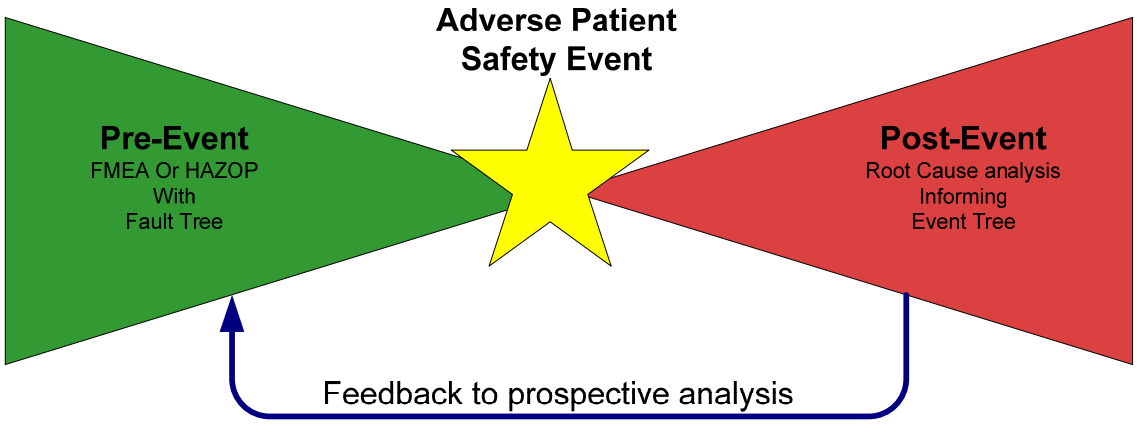

Figure 7-2. The Bow Tie methodology.

Although not covered in this research, Root Cause Analysis (RCA) is a method advocated by the NPSA and commonly employed in the NHS(National Patient Safety Agency, 2006). Although the learning from RCA's is valuable, they tend to be repeated for each investigation carried out following a serious untoward event. Event Trees are ideal for capturing this post-event knowledge as in the red section of Figure 7-2. The further knowledge gained from the combined results form a number of RCA's can then be used to feed back to the prospective analysis in order to make improvements to the system and hazard barriers. Now that the methods themselves have been shown to be applicable to healthcare, this combined methodology can be tested and validated.

The NPSA have published a set of events that are described as 'Never Events' (NPSA, 2009). As the name suggests, these are things that should never happen. There are eight of these (see Figure 7-3) and trusts are expected to carry out a formal investigation including a root cause analysis whenever such an event occurs. It would seem logical that these should be the first to benefit from a structured, formal approach to hazard analysis that makes use of these RCAs to update knowledge and contribute to identifying hazard barriers. Since the NPSA is already collecting these RCA's and they have been tasked with learning from the NHS and sharing such knowledge, it would seem they are best placed to take ownership of this approach and administer it centrally for the benefit of the whole NHS.

- Wrong site surgery
- Retained instrument post-operation
- Wrong route administration of chemotherapy
- Misplaced naso or orogastric tube not deteced prior to use
- Inpatient suicide using non-collapsible rails
- Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners
- In-hospital maternal death from post-partum haemorrhage after elective caesarean section
- Intravenous administration of mis-selected concentrated potassium chloride

Figure 7-3. List of Never Events.

Although Never Events are important and there would be clear benefit to patients if they were prevented, they are still very specific and may be the result of common systemic failures. In order to take these into consideration, at least one level of abstraction needs to be observed. These abstract levels or 'subsystems' would contain many of the Never Events as hazards, allowing common causes and systemic barriers to be addressed.

From a literature review, the informal views of two nurses and a consultant anaesthetist combined with the author's experience in healthcare, six categories of therapies that may be considered to form some of these subsystems were identified: Drugs, Fluids, Gases, Nutrition, Physical and Resuscitation. These were then further divided into types as follows:

Drugs; oral

> These are usually medications given in either tablet or liquid form, taken orally and swallowed on their own or with water. There are numerous types and almost every patient will have some form of oral medication during a stay on a ward.
>
> A number of fairly obvious hazards exist and some complex issues such as allergies or interactions between medications as well as human factors need to be considered in the management of these therapies.

Drugs; single bolus (Crompton, 2003)

> These are usually administered by needle injection and are numerous in type. There are many similarities to oral medications with some added issues such as infection due to piercing the skin, air embolism and the danger of sharps injuries to staff (Vincent, 2006b; Jacobson and Murray, 2007b; Cheng, 2004).

Drugs; Continuous infusion (Jacobson and Murray, 2007b)

> Some medications are delivered intravenously via slow continuous infusion. This requires the use of an infusion device (Jacobson and Murray, 2007b; Khandpur, 2005a) such as a syringe driver or volumetric

pump. There are all the hazards of injected medications as well as those associated with the use of infusion devices and venous cannula placement. The medications also often carry high risk; being critical to the patient's treatment, potentially harmful or a controlled narcotic substance.

Fluids; 'Uncontrolled' infusion (Jacobson and Murray, 2007b)

Fluids are different from *Drugs* in this classification in that they are not manufactured pharmaceuticals, but naturally occurring substances such as water or blood (sometimes with additives). 'Uncontrolled' infusions are those driven by gravity and regulated by a simple roller clamp. The rate of infusion is estimated by counting the number of drops per minute through a sight glass.

Fluids; 'Controlled' infusion (Jacobson and Murray, 2007b; Khandpur, 2005a)

These are similar to those administered by 'uncontrolled' infusion except that use is made of an infusion device, usually a volumetric pump, to deliver a more precise volume. The infusion pumps also monitor the therapy and provide alarms to alert ward staff of occlusions or fluid bag depletions. If blood is being infused, the device must be specifically designed for this use as blood cells are easily damaged by the mechanical action of some types of pump.

Gases; Nitrous Oxide (N_2O) (BOC Medical, 2008)

This is a mild narcotic with analgesic properties, normally mixed with oxygen. Other than its use when combined with other substances in anaesthesia during surgery, it is most often used during labour, pre-mixed in the form of 'Entonox' (50% N_2O, 50% O_2). The hazards pose relatively low risks, but prolonged use is to be avoided (BOC Medical, 2008). It is not often used on other wards.

Nutrition; Nasogastric feeding

Not very often used on general wards, nasogastric feeding is administered to patients who cannot eat or drink in the normal way, but have a functional gastric system. A tube is passed via the nasal passages into the oesophagus and specially formulated feed is pumped directly into the stomach. The most serious hazard is probably that of placement of the tube to prevent feed being passed into the lungs via the trachea (National Patient Safety Agency 2005; Gharib et al., 1996).

Physical; Physiotherapy

Many patients benefit from physiotherapy as part of a rehabilitation regime after surgery, serious injury or prolonged inactivity. There is a wide range of treatments ranging from massage to laser therapy. The treatments are often personally tailored to a patient and practitioners have to be highly skilled.

Resuscitation; Suction

> During resuscitation, sputum and other fluids often have to be suctioned away. Suction is either provided through the use of a piped vacuum supply, a free standing machine or by means of a venturi device on an air or oxygen cylinder. Fluids are collected in a jar or fluid bag and need to be disposed of as biological waste. Care must be taken when suctioning the mouth and throat not to harm the patient or cause hypoxia by sucking oxygenated air from the lungs.

Resuscitation; Defibrillation (Jacobson and Murray, 2007a)

> Defibrillation is used to bring a heart in ventricular fibrillation (Van Wynsberghe et al., 1995a) back into normal sinus rhythm (Clark et al., 1998). This is an expert procedure that involves the discharge of up to 360 Joules across a patient's chest and into the heart muscle from as much as 4000 Volts and 50 Ampere over a few milliseconds (Jacobson and Murray, 2007a; Khandpur, 2005b).

To the author's knowledge, none of these therapeutic subsystems have been the subject of published structured, systematic hazard analysis.

7.7 Final Word

There is a marked distinction between healthcare and many other endeavour models. Most industrial and business processes are carefully designed with a more or less predictable pattern of events. Healthcare, in a similar way to military practice, or even photography, has evolved in a more artful manner. Pockets of highly defined tasks reside in a complex system with a chaotic character, resulting in a structure with many vagaries and outcomes that would be difficult to predict. It is highly dynamic and those practicing their professions within it cannot therefore be constrained within an artificially rigid framework.

If someone were to try to re-design healthcare in order to make it more mechanistic, it may well become more predictable and perhaps even statistically more reliable. It would seem however that in doing so, those that make it work in its current form may become alienated and those needing care might become distrustful of a system that is more focused on process than people.

This however does not preclude the use of checklists (Gawande, 2007) and the mapping and definition of many of the processes within healthcare. Much of the autonomy of doctors and the humanitarian focus of professional nursing can be maintained by ensuring their inclusion as '*intelligent autonomous agents*' within a complex systems analysis framework (Nilsson and Darley, 2006; Nowak and Lamont, 2008).

This thesis has demonstrated, by way of a thorough empirically based evaluation, that prospective hazard analysis methods such as FMEA, FTA and HAZOP can be effectively applied to ward based therapies. It has also shown that the systems definitions used to make sense of the complexity of the healthcare context can be used together with the formal structures of these hazard analyses to capture some of the tacit knowledge held by the professionals working in the system. This research has paved the way for the

use of these methods to shift the emphasis away from the current ‘rearward’ view employed for learning from mistakes in healthcare, to a more ‘forward’ one where hazards are anticipated through a prospective viewpoint. This new methodology, in which both viewpoints have merit and function, should reduce both the frequency and severity of many untoward incidents through the structured dissemination of this captured knowledge. This would promote a culture in which lessons learnt are shared and preventative and mitigatory barriers can be designed and maintained by reference to objective analysis.

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Appendix A ：The Observational Study

A.1 Information sheet.

A survey is being conducted on the use and administration of Oxygen on hospital wards.

Title of the research:

The evaluation of risk to patients on Oxygen Therapy in hospital wards.

How will it affect patients?

This work will not adversely affect the treatment or care of patients, and will not interfere with the normal operation of the department.

No personally identifiable information will be collected.

A researcher will be observing the performance of the Oxygen delivery equipment and the actions of people on the ward. The researcher may on occasion take readings from the Oxygen delivery equipment in use. Discretion will be used in order to protect patient privacy and dignity. Patients will not be asked any questions about themselves. No participation is required from the patient.

How will it affect staff?

The normal operation of the department or ward will not be affected. A researcher will be observing the performance of the Oxygen delivery equipment and the actions of people on the ward. The researcher may on occasion ask questions about what activities have been carried out in relation to a patient receiving Oxygen. No personally identifiable information about the patient or staff will be collected. The researcher will not become involved in any clinical activity. If a potentially harmful or dangerous situation is observed, the researcher will discreetly advise a member of staff.

Who is conducting the research?

The research is being conducted through collaboration between the Hospital Trust and Cranfield University. The same researcher will be present on all occasions, and will be wearing identification.

What is the purpose of the research?

Information is being gathered on how oxygen is used in hospitals in order to assess the potential risks to patients receiving oxygen. This research will be used, along with other research, to help make oxygen therapy even safer than at present.

If you have any concerns or questions, please do not hesitate to ask the researcher. If you would prefer, you may contact the Trust research office for further information.

If you have any complaints, the normal hospitals complaints procedure is available to you. Please ask a member of staff.

Thank you for your interest in this research.

A.2 Notice of Research Activity

Notice of research activity.

Please note that observational research activity is taking place on this ward.

This will in no way adversely affect your treatment or care.

For further information please ask a member of staff.

A.3 Observational Study Tables

Table Appendix A.3-1 List of Category - Subcategory pairs and their frequency.

Event Categories	Event Subcategories	Count
Nursing Tasks	Patient Monitoring	27
Patient Transfer	Patient Arrival	26
Nursing Tasks	Other Therapy	24
Therapy Adjustment	Supply Change	23
Patient Actions	Accessory Displacement	19
Patient Actions	Patient Sleeping	16
Nurse Actions	Failure To Act	16
Therapy Adjustment	Accessory Change	16
Therapy Administration/Monitoring	Accessory Displacement	15
Patient Actions	Patient Talking	14
Accessory Displacement		14
Therapy Adjustment	Therapy Discontinued	11
Nurse Actions	Accessory Adjustment	11
Patient Actions	Patient Eating/Drinking	11
Patient Arrival	Supply Change	10
Therapy Adjustment	Therapy Flow Rate	9
Therapy Administration/Monitoring	Failure To Act	9
Nurse Actions	Accessory Displacement	8
Doctor Actions	Examination	8
Nurse Actions	Patient Posture/Position	8
Nurse Actions	Patient Monitoring	8
Nursing Tasks	Patient Transfer	7
Therapy Administration/Monitoring	Supply Change	7
Patient Condition	Nausea or Vomiting	6
Nurse Actions	Nursing Tasks	6
Patient Actions	Patient Posture/Position	6
Nurse Actions	Remedial Action	6
Therapy Administration/Monitoring	Tubing Disconnect	5
Therapist Actions	Other Therapy	5
Nursing Tasks	Patient Bed/Chair Transfer	5
Nurse Actions	Therapy Discontinued	5
Patient Monitoring	Monitoring Error	5
Nursing Tasks	Patient Posture/Position	5
Clinical Actions	Examination	5
Nursing Tasks	Patient Hand-Over	4
Patient Transfer	Supply Change	4
Patient Actions	Call For Assistance	4
Other Therapy	Medication	4
First Contact	Accessory Displacement	4
Patient Actions	Accessory Adjustment	4
Therapy Administration/Monitoring	Therapy Started	4
Visitor Actions	Patient Talking	4
Nursing Tasks	Patient Care	4
Clinical Actions	Other Therapy	4
Nurse Actions	Environmental Factor	4
Therapy Adjustment	Accessory Adjustment	4
Nurse Actions	Communication Issues	3

Event Categories	Event Subcategories	Count
Patient Actions	Patient Monitoring	3
Therapy Administration/Monitoring	Therapy Stopped	3
Doctor Actions	Clinical Actions	3
Human Factors	Distraction	3
First Contact	Normal Function	3
Therapy Administration/Monitoring	Cylinder Depletion	3
Therapy Administration/Monitoring	Accessory Adjustment	3
Nurse Actions	Medication	3
Researcher Actions	First Contact	3
Patient Comfort	Nature Calls	3
Visitor Actions	Patient Comfort	3
Doctor Actions	Patient Monitoring	3
Doctor Actions	Other Therapy	3
Doctor Actions	Failure To Act	3
Failure To Act	Accessory Displacement	3
Communication Issues	Patient Hand-Over	3
Nurse Actions	Therapy Started	2
Nurse Actions	Patient Care	2
Nurse Actions	Setup Error	2
Nurse Actions	Patient Safety	2
Patient Actions	Patient Co-operation	2
Patient Actions	Patient Comfort	2
Patient Actions	Other Therapy	2
Patient Actions	Medication	2
Medication	Normal Function	2
Nursing Tasks	Accessory Displacement	2
Nursing Tasks	Bed sheets changed	2
Nursing Tasks	Examination	2
Nursing Tasks	Medication	2
Normal Function	First Contact	2
Nurse Actions	Examination	2
Nursing Tasks	Therapy Administration/Monitoring	2
Nursing Tasks	Patient Talking	2
Nurse Actions	Equipment check	2
Normal Function		2
Equipment Disconnect	Patient Monitoring	2
Environmental Factor	Surplus Equipment	2
Patient Transfer	Bed space Move	2
Therapy Administration/Monitoring	Normal Function	2
Porter Actions	Inappropriate Action	2
Therapy Adjustment	Therapy Stopped	2
Clinical Actions	Patient Care	2
Therapy Administration/Monitoring	Therapy Flow Rate	2
Therapy Administration/Monitoring	Obscured View	2
Procedural	Prescription	2
Patient Talking		2
Therapist Actions	Therapy Adjustment	2
Patient Monitoring	Failure To Act	2
Patient Eating/Drinking	Accessory Displacement	2
Communication Issues	Patient Notes	2
Patient Disconnection	Therapy Administration/Monitoring	2

Event Categories	Event Subcategories	Count
Setup Error	Therapy Administration/Monitoring	2
External Contractor Actions	Patient Talking	2
Patient Co-operation	Failure To Act	2
Communication Issues	Failure To Act	1
Communication Issues	Patient Condition	1
Communication Issues	Call For Assistance	1
Nurse Actions	Cylinder Exchange	1
Communication Issues	Impared Speech	1
Nurse Actions	Lack of Staff	1
Consultant Actions	Examination	1
Clinical Actions	Patient Posture/Position	1
Nurse Actions	Bed space Move	1
Clinical Actions	Patient Monitoring	1
Clinical Actions	Patient Bed/Chair Transfer	1
Nurse Actions	Organisational Factor	1
Nurse Actions	Other Therapy	1
Clinical Actions	Accessory Change	1
Accessory Poor Fit	Physical Obstruction	1
Accessory Displacement	Patient Talking	1
Accessory Displacement	Patient Actions	1
Accessory Displacement	Failure To Act	1
Clinical Actions	Supply Change	1
Human Factors	Surplus Equipment	1
Examination	Communication Issues	1
Equipment Failure	Other Therapy	1
First Contact	Patient Actions	1
Human Factors	Communication Issues	1
Equipment Failure	Accessory Failure	1
Human Factors	Other Therapy	1
Equipment check	Normal Function	1
Human Factors	Patient Comfort	1
Equipment Change-over	Patient Monitoring	1
Environmental Factor	Tubing Pinched	1
Domestic Staff Actions	Patient Eating/Drinking	1
Environmental Factor	Technician Actions	1
Doctor Actions	Communication Issues	1
Environmental Factor	Remedial Action	1
Environmental Factor	Patient Access	1
Environmental Factor	Obstructed by Cylinder	1
Environmental Factor	Inappropriate Action	1
Environmental Factor	Human Factors	1
Environmental Factor	Equipment Missing/Unavailable	1
Failure To Act	Therapy Administration/Monitoring	1
Environmental Factor	Call For Assistance	1
Equipment Failure	Bed Fault	1
Doctor Actions	Therapy Discontinued	1
Doctor Actions	Remedial Action	1
Human Factors	Setup Error	1
Researcher Actions		1
Nursing Tasks (Another Patient)	Patient Transfer	1
Technician Actions	Mobile X-ray	1
Technician Actions	Failure To Act	1
Technician Actions	Environmental Factor	1
Setup Error	Therapy Humidification	1

Event Categories	Event Subcategories	Count
Setup Error	Bubble Tubing	1
Setup Error	Accessory Displacement	1
Therapist Actions	Examination	1
Researcher Actions	Therapy Administration/Monitoring	1
Therapist Actions	Failure To Act	1
Procedural	Patient Transfer	1
Procedural	Patient Arrival	1
Porter Actions	Remedial Action	1
Patient Transfer	Patient Bed/Chair Transfer	1
Patient Transfer	Nursing Tasks	1
Patient Transfer	Normal Function	1
Patient Transfer	Communication Issues	1
Setup Error	Accessory Choice Error	1
Therapy Administration/Monitoring	Setup Error	1
Visitor Actions	Patient Safety	1
Visitor Actions	Environmental Factor	1
Visitor Actions		1
Therapy Started	Other Therapy	1
Therapy Discontinued	Nursing Tasks	1
Therapy Discontinued	Nurse Actions	1
Therapy Discontinued	Normal Function	1
Therapist Actions	Communication Issues	1
Therapy Administration/Monitoring	Therapy Adjustment	1
Patient Safety	Procedural	1
Therapy Administration/Monitoring	Remedial Action	1
Therapy Administration/Monitoring	Patient Monitoring	1
Therapy Administration/Monitoring	Accessory Disconnect	1
Therapy Adjustment	Therapy Started	1
Therapist Actions	Therapy Administration/Monitoring	1
Therapist Actions	Patient Talking	1
Therapist Actions	Normal Function	1
Therapy Administration/Monitoring	Therapy Humidification	1
Nursing Tasks	Patient Admission	1
Patient Actions	Confused Thrashing	1
Other Therapy	Remedial Action	1
Visitor Actions	Tampering	1
Organisational Factor	Lack of Staff	1
Nursing Tasks	Therapy Started	1
Nursing Tasks	Therapy Discontinued	1
Nursing Tasks	Patient Eating/Drinking	1
Patient Sleeping	Normal Function	1
Nursing Tasks	Patient Comfort	1
Patient Actions	Patient Condition	1
Nursing Tasks	Nature Calls	1
Nursing Tasks	Bed space Move	1
Nursing Tasks		1
Nurse Actions	Tubing Disconnect	1
Nurse Actions	Therapy Administration/Monitoring	1
Nurse Actions	Supply Fail	1
Nurse Actions	Patient Transfer	1

Event Categories	Event Subcategories	Count
Nursing Tasks	Patient Condition	1
Patient Condition	Patient Confusion	1
Nurse Actions	Patient Comfort	1
Patient Safety	Patient Condition	1
Patient Posture/Position	Accessory Displacement	1
Patient Posture/Position		1
Patient Monitoring	Patient Entanglement	1
Patient Disconnection	Accessory Displacement	1
Patient Co-operation	Nursing Tasks	1
Patient Actions	Inappropriate Action	1
Patient Co-operation	Accessory Displacement	1
Patient Actions	Nature Calls	1
Patient Condition		1
Patient Arrival	Patient Transfer	1
Patient Arrival	Patient Monitoring	1
Patient Admission	Supply Change	1
Patient Actions	Tampering	1
Patient Actions	Patient Safety	1
Patient Actions	Patient Entanglement	1
Patient Sleeping		1
Patient Co-operation	Nurse Actions	1

Table Appendix A.3-2 Categorical combinations and outcomes analysis.

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Patient Transfer	Patient Arrival	Nursing Task	Benign	Neutral	23
Therapy Adjustment	Supply Change	Therapy Setup	Remedial Proactive	Decreased Probability of Failure	15
Accessory Displacement	.	Therapy Setup	Adverse Major	Increased Probability of Failure	11
Patient Actions	Patient Sleeping	Patient Action	Benign	Neutral	11
Nursing Tasks	Patient Monitoring	Monitoring	Benign	Decreased Probability of Failure	10
Patient Actions	Accessory Displacement	Patient Action	Adverse Minor	Increased Probability of Failure	10
Patient Actions	Patient Talking	Patient Action	Benign	Neutral	10
Patient Arrival	Supply Change	Therapy Setup	Benign	Decreased Probability of Failure	10
Therapy Adjustment	Accessory Change	Therapy Setup	Benign	Neutral	10
Therapy Administration/Monitoring	Accessory Displacement	Therapy Setup	Adverse Minor	Increased Probability of Failure	8
Nursing Tasks	Patient Monitoring	Nursing Task	Benign	Neutral	7
Therapy Administration/Monitoring	Failure To Act	Therapy Setup	Adverse Major	Increased Probability of Failure	7
Nursing Tasks	Other Therapy	Other Therapy	Benign	Neutral	6
Patient Actions	Patient Eating/Drinking	Patient Action	Benign	Neutral	6
Patient Actions	Patient Posture/Position	Patient Action	Adverse Minor	Increased Probability of Failure	6
Audit Only	Normal Function	Therapy Setup	Benign	Neutral	5
Doctor Actions	Examination	Clinical	Benign	Decreased Probability of Failure	5
Nursing Tasks	Other Therapy	Other Therapy	Benign	Undetermined	5
Therapy Adjustment	Therapy Discontinued	Therapy Setup	Benign	Neutral	5
Audit Only	Normal Function	Therapy Setup	Benign	Undetermined	4
Nurse Actions	Failure To Act	Therapy Setup	Adverse Major	Increased Probability of Failure	4
Patient Transfer	Supply Change	Therapy Setup	Benign	Increased Probability of Failure	4

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Therapy Adjustment	Therapy Discontinued	Therapy Setup	Undetermined	Undetermined	4
Therapy Administration/Monitoring	Supply Change	Therapy Setup	Benign	Increased Probability of Failure	4
Accessory Displacement	.	Therapy Setup	Adverse Minor	Increased Probability of Failure	3
Clinical Actions	Examination	Clinical	Benign	Decreased Probability of Failure	3
Failure To Act	Accessory Displacement	Therapy Setup	Adverse Major	Increased Probability of Failure	3
Nurse Actions	Accessory Adjustment	Therapy Setup	Remedial Reactive	Improvement	3
Nurse Actions	Accessory Displacement	Nursing Task	Adverse Minor	Increased Probability of Failure	3
Nurse Actions	Environmental Factor	Equipment	Adverse Minor	Increased Probability of Failure	3
Nurse Actions	Failure To Act	Monitoring	Adverse Major	Increased Probability of Failure	3
Nurse Actions	Failure To Act	Therapy Setup	Adverse Major	Undetermined	3
Nurse Actions	Patient Monitoring	Monitoring	Remedial Reactive	Decreased Probability of Failure	3
Nurse Actions	Patient Posture/Position	Patient Safety	Remedial Reactive	Improvement	3
Nursing Tasks	Other Therapy	Nursing Task	Undetermined	Undetermined	3
Other Therapy	Medication	Other Therapy	Adverse Minor	Discomfort	3
Patient Actions	Patient Eating/Drinking	Patient Action	Benign	Increased Probability of Failure	3
Patient Actions	Patient Sleeping	Patient Action	Benign	Increased Probability of Failure	3
Patient Actions	Patient Talking	Patient Action	Benign	Increased Probability of Failure	3
Patient Condition	Nausea or Vomiting	Patient Condition	Adverse Minor	Increased Probability of Failure	3
Patient Monitoring	Monitoring Error	Monitoring	Adverse Major	Increased Probability of Failure	3
Researcher Actions	First Contact	Actions by Others	Benign	Neutral	3
Therapy Adjustment	Supply Change	Therapy Setup	Benign	Decreased Probability of Failure	3
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Benign	Undetermined	3
Therapy Administration/Monitoring	Accessory Displacement	Therapy Setup	Adverse Major	Undetermined	3
Audit Only	Patient Sleeping	Patient Action	Benign	Undetermined	2
Communication Issues	Patient Hand-Over	Communication	Adverse Major	Increased Probability of Failure	2
Environmental Factor	Surplus Equipment	Equipment	Adverse Minor	Increased Probability of Failure	2
External Contractor Actions	Patient Talking	Actions by Others	Benign	Neutral	2
First Contact	Accessory Displacement	Therapy Setup	Adverse Major	Increased Probability of Failure	2
First Contact	Normal Function	Therapy Setup	Benign	Undetermined	2
Medication	Normal Function	Therapy Setup	Benign	Neutral	2
Normal Function		Actions by Others	Benign	Neutral	2
Normal Function	First Contact	Patient Safety	Benign	Neutral	2
Nurse Actions	Failure To Act	Therapy Setup	Adverse Minor	Increased Probability of Failure	2
Nurse Actions	Nursing Tasks	Nursing Task	Benign	Neutral	2
Nurse Actions	Nursing Tasks	Nursing Task	Benign	Undetermined	2
Nurse Actions	Patient Posture/Position	Nursing Task	Benign	Undetermined	2
Nurse Actions	Remedial Action	Patient Action	Remedial Reactive	Improvement	2
Nurse Actions	Setup Error	Therapy Setup	Adverse Minor	Increased Probability of Failure	2

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Nurse Actions	Therapy Discontinued	Therapy Setup	Benign	Neutral	2
Nursing Tasks	Patient Bed/Chair Transfer	Nursing Task	Benign	Neutral	2
Nursing Tasks	Patient Hand-Over	Communication	Benign	Decreased Probability of Failure	2
Nursing Tasks	Patient Monitoring	Monitoring	Remedial Proactive	Decreased Probability of Failure	2
Nursing Tasks	Patient Monitoring	Nursing Task	Benign	Decreased Probability of Failure	2
Nursing Tasks	Patient Transfer	Nursing Task	Benign	Increased Probability of Failure	2
Nursing Tasks	Patient Transfer	Nursing Task	Benign	Undetermined	2
Nursing Tasks	Patient Transfer	Nursing Task	Undetermined	Undetermined	2
Patient Actions	Accessory Adjustment	Patient Action	Remedial Other	Improvement	2
Patient Actions	Accessory Displacement	Patient Action	Adverse Major	Increased Probability of Failure	2
Patient Actions	Accessory Displacement	Patient Action	Adverse Minor	Discomfort	2
Patient Actions	Patient Sleeping	Patient Action	Benign	Undetermined	2
Patient Comfort	Nature Calls	Patient Comfort	Adverse Minor	Next Event Trigger	2
Patient Condition	Nausea or Vomiting	Patient Condition	Adverse Minor	Discomfort	2
Patient Eating/Drinking	Accessory Displacement	Patient Action	Adverse Minor	Increased Probability of Failure	2
Patient Monitoring	Failure To Act	Monitoring	Adverse Minor	Increased Probability of Failure	2
Patient Monitoring	Monitoring Error	Monitoring	Adverse Minor	Increased Probability of Failure	2
Patient Talking		Patient Action	Benign	Neutral	2
Patient Transfer	Patient Arrival	Nursing Task	Benign	Undetermined	2
Setup Error	Therapy Administration/Monitoring	Therapy Setup	Adverse Minor	Undetermined	2
Therapist Actions	Other Therapy	Other Therapy	Benign	Undetermined	2
Therapist Actions	Therapy Adjustment	Therapy Setup	Undetermined	Undetermined	2
Therapy Adjustment	Accessory Adjustment	Therapy Setup	Benign	Neutral	2
Therapy Adjustment	Accessory Change	Therapy Setup	Benign	Undetermined	2
Therapy Adjustment	Supply Change	Therapy Setup	Benign	Increased Probability of Failure	2
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Remedial Reactive	Undetermined	2
Therapy Administration/Monitoring	Accessory Displacement	Therapy Setup	Adverse Major	Increased Probability of Failure	2
Therapy Administration/Monitoring	Cylinder Depletion	Therapy Setup	Adverse Major	Undetermined	2
Therapy Administration/Monitoring	Normal Function	Therapy Setup	Benign	Neutral	2
Therapy Administration/Monitoring	Obscured View	Monitoring	Adverse Minor	Increased Probability of Failure	2
Therapy Administration/Monitoring	Supply Change	Therapy Setup	Benign	Decreased Probability of Failure	2
Therapy Administration/Monitoring	Tubing Disconnect	Therapy Setup	Adverse Minor	Increased Probability of Failure	2
Visitor Actions	Patient Talking	Actions by Others	Benign	Neutral	2
Accessory Displacement	Failure To Act	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Accessory Displacement	Patient Actions	Patient Action	Adverse Minor	Undetermined	1
Accessory Displacement	Patient Talking	Therapy Setup	Adverse Minor	Undetermined	1
Accessory Poor Fit	Physical Obstruction	Equipment	Adverse Minor	Increased Probability of Failure	1
Clinical Actions	Accessory Change	Clinical	Remedial Reactive	Improvement	1
Clinical Actions	Examination	Actions by Others	Benign	Decreased Probability of Failure	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Clinical Actions	Examination	Clinical	Benign	Neutral	1
Clinical Actions	Other Therapy	Clinical	Remedial Reactive	Improvement	1
Clinical Actions	Other Therapy	Other Therapy	Adverse Minor	Discomfort	1
Clinical Actions	Other Therapy	Other Therapy	Adverse Minor	Undetermined	1
Clinical Actions	Other Therapy	Other Therapy	Remedial Reactive	Improvement	1
Clinical Actions	Patient Bed/Chair Transfer	Actions by Others	Benign	Neutral	1
Clinical Actions	Patient Care	Clinical	Remedial Other	Undetermined	1
Clinical Actions	Patient Care	Clinical	Undetermined	Undetermined	1
Clinical Actions	Patient Monitoring	Clinical	Benign	Decreased Probability of Failure	1
Clinical Actions	Patient Posture/Position	Clinical	Benign	Neutral	1
Clinical Actions	Supply Change	Actions by Others	Benign	Neutral	1
Communication Issues	Call For Assistance	Communication	Adverse Minor	Discomfort	1
Communication Issues	Failure To Act	Communication	Adverse Minor	Increased Probability of Failure	1
Communication Issues	Impaired Speech	Communication	Adverse Minor	Increased Probability of Failure	1
Communication Issues	Patient Condition	Patient Condition	Adverse Minor	Increased Probability of Failure	1
Communication Issues	Patient Hand-Over	Communication	Benign	Decreased Probability of Failure	1
Communication Issues	Patient Notes	Communication	Adverse Major	Delay	1
Communication Issues	Patient Notes	Communication	Adverse Minor	Increased Probability of Failure	1
Consultant Actions	Examination	Clinical	Benign	Decreased Probability of Failure	1
Doctor Actions	Clinical Actions	Actions by Others	Undetermined	Undetermined	1
Doctor Actions	Clinical Actions	Clinical	Benign	Neutral	1
Doctor Actions	Clinical Actions	Clinical	Remedial Proactive	Decreased Probability of Failure	1
Doctor Actions	Communication Issues	Communication	Adverse Minor	Next Event Trigger	1
Doctor Actions	Examination	Clinical	Benign	Neutral	1
Doctor Actions	Examination	Clinical	Benign	Undetermined	1
Doctor Actions	Examination	Clinical	Undetermined	Decreased Probability of Failure	1
Doctor Actions	Failure To Act	Actions by Others	Adverse Major	Increased Probability of Failure	1
Doctor Actions	Failure To Act	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Doctor Actions	Failure To Act	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Doctor Actions	Other Therapy	Clinical	Benign	Neutral	1
Doctor Actions	Other Therapy	Clinical	Benign	Undetermined	1
Doctor Actions	Other Therapy	Other Therapy	Benign	Neutral	1
Doctor Actions	Patient Monitoring	Monitoring	Adverse Major	Increased Probability of Failure	1
Doctor Actions	Patient Monitoring	Monitoring	Remedial Proactive	Decreased Probability of Failure	1
Doctor Actions	Patient Monitoring	Monitoring	Remedial Reactive	Improvement	1
Doctor Actions	Remedial Action	Patient Safety	Remedial Reactive	Improvement	1
Doctor Actions	Therapy Discontinued	Therapy Setup	Undetermined	Undetermined	1
Domestic Staff Actions	Patient Eating/Drinking	Actions by Others	Benign	Undetermined	1
Environmental Factor	Call For Assistance	Communication	Adverse Major	Increased Probability of Failure	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Environmental Factor	Equipment Missing/Unavailable	Resources	Adverse Major	Increased Probability of Failure	1
Environmental Factor	Human Factors	Patient Safety	Adverse Minor	Near Miss	1
Environmental Factor	Inappropriate Action	Actions by Others	Undetermined	Undetermined	1
Environmental Factor	Obstructed by Cylinder	Equipment	Adverse Minor	Increased Probability of Failure	1
Environmental Factor	Patient Access	Nursing Task	Adverse Minor	Increased Probability of Failure	1
Environmental Factor	Remedial Action	Equipment	Remedial Reactive	Improvement	1
Environmental Factor	Technician Actions	Actions by Others	Undetermined	Increased Probability of Failure	1
Environmental Factor	Tubing Pinched	Equipment	Adverse Major	Increased Probability of Failure	1
Equipment Change-over	Patient Monitoring	Equipment	Benign	Increased Probability of Failure	1
Equipment check	Normal Function	Equipment	Adverse Minor	Increased Probability of Failure	1
Equipment Disconnect	Patient Monitoring	Monitoring	Adverse Major	Increased Probability of Failure	1
Equipment Disconnect	Patient Monitoring	Monitoring	Adverse Minor	Increased Probability of Failure	1
Equipment Failure	Accessory Failure	Equipment	Adverse Minor	Increased Probability of Failure	1
Equipment Failure	Bed Fault	Equipment	Adverse Major	Near Miss	1
Equipment Failure	Other Therapy	Other Therapy	Adverse Major	Discomfort	1
Examination	Communication Issues	Communication	Benign	Increased Probability of Failure	1
Failure To Act	Therapy Administration/Monitoring	Monitoring	Adverse Major	Near Miss	1
First Contact	Accessory Displacement	Therapy Setup	Adverse Major	Undetermined	1
First Contact	Accessory Displacement	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
First Contact	Normal Function	Therapy Setup	Benign	Neutral	1
First Contact	Patient Actions	Patient Action	Adverse Minor	Increased Probability of Failure	1
Human Factors	Communication Issues	Communication	Adverse Major	Increased Probability of Failure	1
Human Factors	Distraction	Actions by Others	Adverse Minor	Increased Probability of Failure	1
Human Factors	Distraction	Other Therapy	Adverse Minor	Increased Probability of Failure	1
Human Factors	Distraction	Patient Safety	Adverse Minor	Increased Probability of Failure	1
Human Factors	Other Therapy	Other Therapy	Adverse Minor	Neutral	1
Human Factors	Patient Comfort	Patient Comfort	Adverse Minor	Discomfort	1
Human Factors	Setup Error	Therapy Setup	Adverse Major	Near Miss	1
Human Factors	Surplus Equipment	Equipment	Adverse Minor	Increased Probability of Failure	1
Nurse Actions	Accessory Adjustment	Equipment	Remedial Reactive	Improvement	1
Nurse Actions	Accessory Adjustment	Nursing Task	Remedial Reactive	Decreased Probability of Failure	1
Nurse Actions	Accessory Adjustment	Patient Action	Remedial Reactive	Improvement	1
Nurse Actions	Accessory Adjustment	Therapy Setup	Benign	Decreased Probability of Failure	1
Nurse Actions	Accessory Adjustment	Therapy Setup	Remedial Other	Decreased Probability of Failure	1
Nurse Actions	Accessory Adjustment	Therapy Setup	Remedial Proactive	Undetermined	1
Nurse Actions	Accessory Adjustment	Therapy Setup	Remedial Reactive	Aversion	1
Nurse Actions	Accessory Adjustment	Therapy Setup	Remedial Reactive	Increased Probability of Failure	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Nurse Actions	Accessory Displacement	Nursing Task	Adverse Minor	Minor Injury/Slight Worsening	1
Nurse Actions	Accessory Displacement	Nursing Task	Benign	Increased Probability of Failure	1
Nurse Actions	Accessory Displacement	Patient Condition	Remedial Reactive	Aversion	1
Nurse Actions	Accessory Displacement	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Nurse Actions	Accessory Displacement	Therapy Setup	Benign	Decreased Probability of Failure	1
Nurse Actions	Bed space Move	Nursing Task	Benign	Neutral	1
Nurse Actions	Communication Issues	Communication	Benign	Decreased Probability of Failure	1
Nurse Actions	Communication Issues	Communication	Benign	Neutral	1
Nurse Actions	Communication Issues	Therapy Setup	Adverse Major	Undetermined	1
Nurse Actions	Cylinder Exchange	Therapy Setup	Remedial Reactive	Improvement	1
Nurse Actions	Environmental Factor	Equipment	Benign	Increased Probability of Failure	1
Nurse Actions	Equipment check	Equipment	Remedial Proactive	Decreased Probability of Failure	1
Nurse Actions	Equipment check	Monitoring	Remedial Proactive	Decreased Probability of Failure	1
Nurse Actions	Examination	Clinical	Undetermined	Undetermined	1
Nurse Actions	Examination	Nursing Task	Benign	Decreased Probability of Failure	1
Nurse Actions	Failure To Act		Adverse Major	Undetermined	1
Nurse Actions	Failure To Act	Communication	Adverse Major	Increased Probability of Failure	1
Nurse Actions	Failure To Act	Equipment	Adverse Major	Increased Probability of Failure	1
Nurse Actions	Failure To Act	Therapy Setup	Adverse Minor	Undetermined	1
Nurse Actions	Lack of Staff	Monitoring	Adverse Minor	Increased Probability of Failure	1
Nurse Actions	Medication	Nursing Task	Benign	Neutral	1
Nurse Actions	Medication	Other Therapy	Benign	Neutral	1
Nurse Actions	Medication	Other Therapy	Benign	Undetermined	1
Nurse Actions	Nursing Tasks	Monitoring	Remedial Proactive	Decreased Probability of Failure	1
Nurse Actions	Nursing Tasks	Nursing Task	Adverse Minor	Discomfort	1
Nurse Actions	Organisational Factor	Actions by Others	Benign	Next Event Trigger	1
Nurse Actions	Other Therapy	Nursing Task	Remedial Other	Improvement	1
Nurse Actions	Patient Care	Nursing Task	Benign	Neutral	1
Nurse Actions	Patient Care	Nursing Task	Benign	Undetermined	1
Nurse Actions	Patient Comfort	Nursing Task	Benign	Neutral	1
Nurse Actions	Patient Monitoring	Monitoring	Adverse Minor	Increased Probability of Failure	1
Nurse Actions	Patient Monitoring	Monitoring	Adverse Minor	Neutral	1
Nurse Actions	Patient Monitoring	Monitoring	Adverse Minor	Undetermined	1
Nurse Actions	Patient Monitoring	Monitoring	Remedial Proactive	Aversion	1
Nurse Actions	Patient Monitoring	Nursing Task	Benign	Neutral	1
Nurse Actions	Patient Posture/Position	Nursing Task	Benign	Neutral	1
Nurse Actions	Patient Posture/Position	Patient Comfort	Benign	Neutral	1
Nurse Actions	Patient Posture/Position	Patient Safety	Remedial Proactive	Aversion	1
Nurse Actions	Patient Safety	Patient Safety	Remedial Proactive	Decreased Probability of Failure	1
Nurse Actions	Patient Safety	Patient Safety	Remedial Proactive	Improvement	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Nurse Actions	Patient Transfer	Nursing Task	Benign	Undetermined	1
Nurse Actions	Remedial Action	Monitoring	Remedial Reactive	Improvement	1
Nurse Actions	Remedial Action	Patient Action	Remedial Reactive	Decreased Probability of Failure	1
Nurse Actions	Remedial Action	Patient Comfort	Remedial Reactive	Improvement	1
Nurse Actions	Remedial Action	Therapy Setup	Remedial Reactive	Improvement	1
Nurse Actions	Supply Fail	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Nurse Actions	Therapy Administration/Monitoring	Therapy Setup	Remedial Reactive	Aversion	1
Nurse Actions	Therapy Discontinued	Therapy Setup	Adverse Major	Minor Injury/Slight Worsening	1
Nurse Actions	Therapy Discontinued	Therapy Setup	Benign	Undetermined	1
Nurse Actions	Therapy Discontinued	Therapy Setup	Undetermined	Undetermined	1
Nurse Actions	Therapy Started	Patient Condition	Remedial Reactive	Aversion	1
Nurse Actions	Therapy Started	Therapy Setup	Remedial Reactive	Improvement	1
Nurse Actions	Tubing Disconnect	Therapy Setup	Adverse Minor	Discomfort	1
Nursing Tasks		Nursing Task	Benign	Neutral	1
Nursing Tasks	Accessory Displacement	Nursing Task	Adverse Minor	Increased Probability of Failure	1
Nursing Tasks	Accessory Displacement	Therapy Setup	Undetermined	Increased Probability of Failure	1
Nursing Tasks	Bed sheets changed	Nursing Task	Benign	Next Event Trigger	1
Nursing Tasks	Bed sheets changed	Nursing Task	Remedial Other	Neutral	1
Nursing Tasks	Bed space Move	Nursing Task	Benign	Neutral	1
Nursing Tasks	Examination	Monitoring	Benign	Decreased Probability of Failure	1
Nursing Tasks	Examination	Nursing Task	Benign	Neutral	1
Nursing Tasks	Medication	Other Therapy	Benign	Neutral	1
Nursing Tasks	Medication	Therapy Setup	Adverse Minor	Discomfort	1
Nursing Tasks	Nature Calls	Nursing Task	Benign	Discomfort	1
Nursing Tasks	Other Therapy		Benign	Neutral	1
Nursing Tasks	Other Therapy	Clinical	Benign	Neutral	1
Nursing Tasks	Other Therapy	Clinical	Remedial Reactive	Undetermined	1
Nursing Tasks	Other Therapy	Nursing Task	Adverse Minor	Discomfort	1
Nursing Tasks	Other Therapy	Nursing Task	Benign	Undetermined	1
Nursing Tasks	Other Therapy	Nursing Task	Remedial Reactive	Undetermined	1
Nursing Tasks	Other Therapy	Nursing Task	Undetermined	Neutral	1
Nursing Tasks	Other Therapy	Other Therapy	Remedial Other	Neutral	1
Nursing Tasks	Other Therapy	Other Therapy	Remedial Reactive	Neutral	1
Nursing Tasks	Other Therapy	Other Therapy	Undetermined	Undetermined	1
Nursing Tasks	Patient Admission	Nursing Task	Benign	Improvement	1
Nursing Tasks	Patient Bed/Chair Transfer	Nursing Task	Benign	Improvement	1
Nursing Tasks	Patient Bed/Chair Transfer	Nursing Task	Benign	Increased Probability of Failure	1
Nursing Tasks	Patient Bed/Chair Transfer	Nursing Task	Undetermined	Undetermined	1
Nursing Tasks	Patient Care	Clinical	Benign	Undetermined	1
Nursing Tasks	Patient Care	Nursing Task	Benign	Neutral	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Nursing Tasks	Patient Care	Patient Condition	Benign	Neutral	1
Nursing Tasks	Patient Care	Patient Condition	Remedial Reactive	Undetermined	1
Nursing Tasks	Patient Comfort	Nursing Task	Benign	Improvement	1
Nursing Tasks	Patient Condition	Nursing Task	Undetermined	Undetermined	1
Nursing Tasks	Patient Eating/Drinking	Nursing Task	Benign	Neutral	1
Nursing Tasks	Patient Hand-Over	Communication	Benign	Neutral	1
Nursing Tasks	Patient Hand-Over	Nursing Task	Benign	Undetermined	1
Nursing Tasks	Patient Monitoring	Monitoring	Benign	Increased Probability of Failure	1
Nursing Tasks	Patient Monitoring	Monitoring	Benign	Neutral	1
Nursing Tasks	Patient Monitoring	Monitoring	Remedial Other	Decreased Probability of Failure	1
Nursing Tasks	Patient Monitoring	Monitoring	Remedial Proactive	Undetermined	1
Nursing Tasks	Patient Monitoring	Nursing Task	Remedial Proactive	Decreased Probability of Failure	1
Nursing Tasks	Patient Monitoring	Nursing Task	Remedial Proactive	Improvement	1
Nursing Tasks	Patient Posture/Position	Nursing Task	Benign	Improvement	1
Nursing Tasks	Patient Posture/Position	Nursing Task	Benign	Increased Probability of Failure	1
Nursing Tasks	Patient Posture/Position	Nursing Task	Benign	Neutral	1
Nursing Tasks	Patient Posture/Position	Patient Comfort	Remedial Other	Undetermined	1
Nursing Tasks	Patient Posture/Position	Patient Condition	Remedial Reactive	Improvement	1
Nursing Tasks	Patient Talking	Communication	Benign	Neutral	1
Nursing Tasks	Patient Talking	Nursing Task	Benign	Decreased Probability of Failure	1
Nursing Tasks	Patient Transfer	Nursing Task	Benign	Neutral	1
Nursing Tasks	Therapy Administration/Monitoring	Therapy Setup	Remedial Other	Improvement	1
Nursing Tasks	Therapy Administration/Monitoring	Therapy Setup	Remedial Proactive	Undetermined	1
Nursing Tasks	Therapy Discontinued	Nursing Task	Benign	Neutral	1
Nursing Tasks	Therapy Started	Nursing Task	Benign	Neutral	1
Nursing Tasks (Another Patient)	Patient Transfer	Nursing Task	Undetermined	Neutral	1
Organisational Factor	Lack of Staff	Resources	Adverse Major	Increased Probability of Failure	1
Other Therapy	Medication	Clinical	Benign	Undetermined	1
Other Therapy	Remedial Action	Patient Condition	Remedial Reactive	Improvement	1
Patient Actions	Accessory Adjustment	Patient Action	Remedial Other	Decreased Probability of Failure	1
Patient Actions	Accessory Adjustment	Therapy Setup	Remedial Other	Improvement	1
Patient Actions	Accessory Displacement		Adverse Minor	Neutral	1
Patient Actions	Accessory Displacement	Patient Action	Adverse Major	Next Event Trigger	1
Patient Actions	Accessory Displacement	Patient Action	Adverse Major	Undetermined	1
Patient Actions	Accessory Displacement	Patient Action	Adverse Minor	Undetermined	1
Patient Actions	Accessory Displacement	Patient Comfort	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Call For Assistance	Communication	Benign	Neutral	1
Patient Actions	Call For Assistance	Patient Action	Benign	Decreased Probability of Failure	1
Patient Actions	Call For Assistance	Patient Action	Remedial Reactive	Decreased Probability of Failure	1
Patient Actions	Call For Assistance	Patient Action	Remedial Reactive	Improvement	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Patient Actions	Confused Thrashing	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Inappropriate Action	Patient Action	Adverse Major	Undetermined	1
Patient Actions	Medication	Patient Action	Adverse Minor	Discomfort	1
Patient Actions	Medication	Patient Action	Benign	Neutral	1
Patient Actions	Nature Calls	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Other Therapy	Other Therapy	Adverse Major	Near Miss	1
Patient Actions	Other Therapy	Patient Safety	Adverse Minor	Undetermined	1
Patient Actions	Patient Comfort	Patient Action	Adverse Minor	Discomfort	1
Patient Actions	Patient Comfort	Patient Action	Benign	Next Event Trigger	1
Patient Actions	Patient Condition	Patient Condition	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Patient Co-operation	Patient Action	Adverse Major	Increased Probability of Failure	1
Patient Actions	Patient Co-operation	Patient Action	Adverse Minor	Undetermined	1
Patient Actions	Patient Eating/Drinking	Patient Action	Adverse Major	Neutral	1
Patient Actions	Patient Eating/Drinking	Patient Action	Benign	Undetermined	1
Patient Actions	Patient Entanglement	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Patient Monitoring	Monitoring	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Patient Monitoring	Monitoring	Remedial Other	Improvement	1
Patient Actions	Patient Monitoring	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Patient Safety	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Actions	Patient Talking	Patient Action	Benign	Undetermined	1
Patient Actions	Tampering	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Admission	Supply Change	Therapy Setup	Benign	Decreased Probability of Failure	1
Patient Arrival	Patient Monitoring	Monitoring	Benign	Neutral	1
Patient Arrival	Patient Transfer	Actions by Others	Benign	Undetermined	1
Patient Comfort	Nature Calls	Patient Comfort	Benign	Neutral	1
Patient Condition		Patient Condition	Adverse Major	Undetermined	1
Patient Condition	Nausea or Vomiting	Patient Condition	Adverse Minor	Undetermined	1
Patient Condition	Patient Confusion	Patient Condition	Adverse Minor	Increased Probability of Failure	1
Patient Co-operation	Accessory Displacement	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Co-operation	Failure To Act	Patient Action	Adverse Minor	Increased Probability of Failure	1
Patient Co-operation	Failure To Act	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Patient Co-operation	Nurse Actions	Nursing Task	Remedial Other	Improvement	1
Patient Co-operation	Nursing Tasks	Patient Comfort	Adverse Minor	Discomfort	1
Patient Disconnection	Accessory Displacement	Monitoring	Adverse Major	Aversion	1
Patient Disconnection	Therapy Administration/Monitoring	Therapy Setup	Adverse Major	Near Miss	1
Patient Disconnection	Therapy Administration/Monitoring	Therapy Setup	Adverse Major	Undetermined	1
Patient Monitoring	Patient Entanglement	Monitoring	Adverse Minor	Increased Probability of Failure	1
Patient Posture/Position		Patient Comfort	Benign	Neutral	1
Patient Posture/Position	Accessory Displacement	Therapy Setup	Adverse Minor	Increased Probability of Failure	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Patient Safety	Patient Condition	Patient Condition	Adverse Major	Increased Probability of Failure	1
Patient Safety	Procedural	Patient Safety	Adverse Minor	Undetermined	1
Patient Sleeping		Patient Action	Benign	Neutral	1
Patient Sleeping	Normal Function	Patient Action	Benign	Neutral	1
Patient Transfer	Bed space Move	Clinical	Benign	Undetermined	1
Patient Transfer	Bed space Move	Nursing Task	Undetermined	Increased Probability of Failure	1
Patient Transfer	Communication Issues	Equipment	Adverse Major	Increased Probability of Failure	1
Patient Transfer	Normal Function	Nursing Task	Undetermined	Undetermined	1
Patient Transfer	Nursing Tasks	Nursing Task	Benign	Neutral	1
Patient Transfer	Patient Arrival	Actions by Others	Benign	Neutral	1
Patient Transfer	Patient Bed/Chair Transfer	Patient Comfort	Benign	Undetermined	1
Porter Actions	Inappropriate Action	Actions by Others	Adverse Major	Increased Probability of Failure	1
Porter Actions	Inappropriate Action	Actions by Others	Adverse Major	Undetermined	1
Porter Actions	Remedial Action	Therapy Setup	Remedial Reactive	Improvement	1
Procedural	Patient Arrival	Actions by Others	Benign	Neutral	1
Procedural	Patient Transfer	Actions by Others	Benign	Neutral	1
Procedural	Prescription	Communication	Adverse Minor	Increased Probability of Failure	1
Procedural	Prescription	Patient Safety	Adverse Minor	Increased Probability of Failure	1
Researcher Actions		Patient Safety	Remedial Reactive	Undetermined	1
Researcher Actions	Therapy Administration/Monitoring	Therapy Setup	Remedial Reactive	Improvement	1
Setup Error	Accessory Choice Error	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Setup Error	Accessory Displacement	Therapy Setup	Adverse Minor	Neutral	1
Setup Error	Bubble Tubing	Therapy Setup	Adverse Minor	Undetermined	1
Setup Error	Therapy Humidification	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Technician Actions	Environmental Factor	Actions by Others	Remedial Other	Improvement	1
Technician Actions	Failure To Act	Actions by Others	Adverse Minor	Increased Probability of Failure	1
Technician Actions	Mobile X-ray	Actions by Others	Benign	Neutral	1
Therapist Actions	Communication Issues	Patient Condition	Benign	Neutral	1
Therapist Actions	Examination	Clinical	Undetermined	Undetermined	1
Therapist Actions	Failure To Act	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Therapist Actions	Normal Function	Actions by Others	Benign	Neutral	1
Therapist Actions	Other Therapy	Actions by Others	Benign	Neutral	1
Therapist Actions	Other Therapy	Other Therapy	Benign	Discomfort	1
Therapist Actions	Other Therapy	Other Therapy	Benign	Neutral	1
Therapist Actions	Patient Talking	Monitoring	Benign	Neutral	1
Therapist Actions	Therapy Administration/Monitoring	Monitoring	Remedial Proactive	Aversion	1
Therapy Adjustment	Accessory Adjustment	Nursing Task	Remedial Proactive	Improvement	1
Therapy Adjustment	Accessory Adjustment	Therapy Setup	Remedial Reactive	Undetermined	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Therapy Adjustment	Accessory Change	Patient Comfort	Remedial Reactive	Aversion	1
Therapy Adjustment	Accessory Change	Therapy Setup	Adverse Major	Next Event Trigger	1
Therapy Adjustment	Accessory Change	Therapy Setup	Benign	Improvement	1
Therapy Adjustment	Accessory Change	Therapy Setup	Remedial Reactive	Improvement	1
Therapy Adjustment	Supply Change	Therapy Setup	Benign	Neutral	1
Therapy Adjustment	Supply Change	Therapy Setup	Remedial Reactive	Aversion	1
Therapy Adjustment	Supply Change	Therapy Setup	Undetermined	Increased Probability of Failure	1
Therapy Adjustment	Therapy Discontinued	Therapy Setup	Benign	Undetermined	1
Therapy Adjustment	Therapy Discontinued	Therapy Setup	Remedial Reactive	Undetermined	1
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Benign	Discomfort	1
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Benign	Neutral	1
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Remedial Other	Undetermined	1
Therapy Adjustment	Therapy Flow Rate	Therapy Setup	Remedial Reactive	Improvement	1
Therapy Adjustment	Therapy Started	Patient Condition	Remedial Reactive	Improvement	1
Therapy Adjustment	Therapy Stopped	Therapy Setup	Adverse Major	Minor Injury/Slight Worsening	1
Therapy Adjustment	Therapy Stopped	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Therapy Administration/Monitoring	Accessory Adjustment	Therapy Setup	Remedial Other	Decreased Probability of Failure	1
Therapy Administration/Monitoring	Accessory Adjustment	Therapy Setup	Remedial Reactive	Aversion	1
Therapy Administration/Monitoring	Accessory Adjustment	Therapy Setup	Remedial Reactive	Improvement	1
Therapy Administration/Monitoring	Accessory Disconnect	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Therapy Administration/Monitoring	Accessory Displacement	Patient Condition	Adverse Minor	Improvement	1
Therapy Administration/Monitoring	Accessory Displacement	Therapy Setup	Undetermined	Undetermined	1
Therapy Administration/Monitoring	Cylinder Depletion	Monitoring	Adverse Major	Near Miss	1
Therapy Administration/Monitoring	Failure To Act	Nursing Task	Adverse Major	Increased Probability of Failure	1
Therapy Administration/Monitoring	Failure To Act	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Therapy Administration/Monitoring	Patient Monitoring	Monitoring	Benign	Decreased Probability of Failure	1
Therapy Administration/Monitoring	Remedial Action	Therapy Setup	Remedial Reactive	Aversion	1
Therapy Administration/Monitoring	Setup Error	Therapy Setup	Adverse Minor	Undetermined	1
Therapy Administration/Monitoring	Supply Change	Therapy Setup	Remedial Proactive	Decreased Probability of Failure	1
Therapy Administration/Monitoring	Therapy Adjustment	Therapy Setup	Remedial Reactive	Improvement	1
Therapy Administration/Monitoring	Therapy Flow Rate	Therapy Setup	Adverse Minor	Increased Probability of Failure	1
Therapy Administration/Monitoring	Therapy Flow Rate	Therapy Setup	Undetermined	Undetermined	1
Therapy Administration/Monitoring	Therapy Humidification	Therapy Setup	Adverse Minor	Undetermined	1
Therapy Administration/Monitoring	Therapy Started	Nursing Task	Benign	Decreased Probability of Failure	1
Therapy Administration/Monitoring	Therapy Started	Nursing Task	Benign	Improvement	1
Therapy Administration/Monitoring	Therapy Started	Therapy Setup	Benign	Neutral	1

Category	Sub-Category	Focus	Event Type	Possible Outcome	Count
Therapy Administration/Monitoring	Therapy Started	Therapy Setup	Remedial Reactive	Aversion	1
Therapy Administration/Monitoring	Therapy Stopped	Nursing Task	Adverse Minor	Increased Probability of Failure	1
Therapy Administration/Monitoring	Therapy Stopped	Nursing Task	Benign	Increased Probability of Failure	1
Therapy Administration/Monitoring	Therapy Stopped	Therapy Setup	Undetermined	Undetermined	1
Therapy Administration/Monitoring	Tubing Disconnect	Therapy Setup	Adverse Major	Increased Probability of Failure	1
Therapy Administration/Monitoring	Tubing Disconnect	Therapy Setup	Adverse Minor	Discomfort	1
Therapy Administration/Monitoring	Tubing Disconnect	Therapy Setup	Undetermined	Undetermined	1
Therapy Discontinued	Normal Function	Therapy Setup	Benign	Undetermined	1
Therapy Discontinued	Nurse Actions	Therapy Setup	Benign	Neutral	1
Therapy Discontinued	Nursing Tasks	Therapy Setup	Benign	Undetermined	1
Therapy Started	Other Therapy	Other Therapy	Remedial Other	Undetermined	1
Visitor Actions		Actions by Others	Benign	Neutral	1
Visitor Actions	Environmental Factor	Equipment	Adverse Minor	Near Miss	1
Visitor Actions	Patient Comfort	Actions by Others	Benign	Increased Probability of Failure	1
Visitor Actions	Patient Comfort	Actions by Others	Benign	Neutral	1
Visitor Actions	Patient Comfort	Patient Comfort	Benign	Improvement	1
Visitor Actions	Patient Safety	Actions by Others	Benign	Decreased Probability of Failure	1
Visitor Actions	Patient Talking	Actions by Others	Benign	Increased Probability of Failure	1
Visitor Actions	Patient Talking	Patient Action	Benign	Neutral	1
Visitor Actions	Tampering	Actions by Others	Adverse Major	Near Miss	1

Table Appendix A.3-3 Hazard Identification from Observed Events.

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Actions by Others	Doctor Actions	Clinical Actions	Undetermined	Undetermined	Incorrect clinical decision or action
Actions by Others	Doctor Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to recognize and act on an imminent therapy failure
Actions by Others	Nurse Actions	Failure To Act	Adverse Major	Undetermined	Failure to recognize and act on an imminent therapy failure
Actions by Others	Technician Actions	Failure To Act	Adverse Minor	Increased Probability of Failure	Failure to recognize and act on an imminent therapy failure
Actions by Others	Domestic Staff Actions	Patient Eating/Drinking	Benign	Undetermined	Unauthorized or inappropriate action by others
Actions by Others	Porter Actions	Inappropriate Action	Adverse Major	Increased Probability of Failure	Unauthorized or inappropriate action by

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					others
Actions by Others	Porter Actions	Inappropriate Action	Adverse Major	Undetermined	Unauthorized or inappropriate action by others
Actions by Others	Environmental Factor	Inappropriate Action	Undetermined	Undetermined	An environmental factor promotes inappropriate action
Actions by Others	Environmental Factor	Technician Actions	Undetermined	Increased Probability of Failure	Non clinical staff rectifying an environmental fault
Actions by Others	Human Factors	Distraction	Adverse Minor	Increased Probability of Failure	Distraction caused by activity on the ward
Actions by Others	Nurse Actions	Organisational Factor	Benign	Next Event Trigger	Latent error causes a failure in communication or process
Actions by Others	Patient Arrival	Patient Transfer	Benign	Undetermined	Patient management errors when patients arrive after transfer
Actions by Others	Visitor Actions	Patient Comfort	Benign	Increased Probability of Failure	Innocent action by visitor to aid patient comfort compromises this therapy
Actions by Others	Visitor Actions	Patient Talking	Benign	Increased Probability of Failure	Patients talking to visitors
Actions by Others	Visitor Actions	Tampering	Adverse Major	Near Miss	Visitors tampering with therapies
Clinical	Clinical Actions	Patient Care	Remedial Other	Undetermined	Clinical activity interfering with the therapy
Clinical	Clinical Actions	Patient Care	Undetermined	Undetermined	Clinical activity interfering with the therapy
Clinical	Therapist Actions	Examination	Undetermined	Undetermined	Clinical activity interfering with the therapy
Clinical	Nursing Tasks	Other Therapy	Remedial Reactive	Undetermined	Administering or adjusting another therapy causes interference with this one
Clinical	Doctor Actions	Other Therapy	Benign	Undetermined	Administering or adjusting another therapy causes interference with this one
Clinical	Nursing Tasks	Patient Care	Benign	Undetermined	Administering or adjusting another therapy causes interference with this one

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Clinical	Patient Transfer	Bed space Move	Benign	Undetermined	Process or patient management errors moving patients from one bed to another
Clinical	Doctor Actions	Examination	Benign	Undetermined	Patient requirement incorrectly assessed
Clinical	Nurse Actions	Examination	Undetermined	Undetermined	General nursing tasks interfering with the therapy
Clinical	Other Therapy	Medication	Benign	Undetermined	Other medication interfering with this therapy
Communication	Human Factors	Communication Issues	Adverse Major	Increased Probability of Failure	Inadequacy of pro forma or another communication tool
Communication	Communication Issues	Call For Assistance	Adverse Minor	Discomfort	Calls for assistance unanswered
Communication	Communication Issues	Failure To Act	Adverse Minor	Increased Probability of Failure	Patient requests or needs unfulfilled
Communication	Communication Issues	Impaired Speech	Adverse Minor	Increased Probability of Failure	Impaired speech due to the face mask or other aspect of the therapy making communication difficult
Communication	Communication Issues	Patient Hand-Over	Adverse Major	Increased Probability of Failure	Communication failures at patient hand-over
Communication	Communication Issues	Patient Notes	Adverse Major	Delay	Missing or incomplete patient notes
Communication	Communication Issues	Patient Notes	Adverse Minor	Increased Probability of Failure	Incorrect information in patient notes
Communication	Doctor Actions	Communication Issues	Adverse Minor	Next Event Trigger	Poor communication from doctors to nursing staff
Communication	Environmental Factor	Call For Assistance	Adverse Major	Increased Probability of Failure	Environmental factors such as noise masking calls for assistance
Communication	Examination	Communication Issues	Benign	Increased Probability of Failure	Communication failures between clinician and patient during an examination
Communication	Nurse Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Nursing staff not responding to requests or orders from doctors

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Communication	Procedural	Prescription	Adverse Minor	Increased Probability of Failure	Prescriptions or treatment orders incorrect or not made
Equipment	Accessory Poor Fit	Physical Obstruction	Adverse Minor	Increased Probability of Failure	Spectacles or other obstructions on the face
Equipment	Environmental Factor	Obstructed by Cylinder	Adverse Minor	Increased Probability of Failure	Position of cylinders at the bed side
Equipment	Environmental Factor	Surplus Equipment	Adverse Minor	Increased Probability of Failure	Surplus equipment cluttering the ward area
Equipment	Human Factors	Surplus Equipment	Adverse Minor	Increased Probability of Failure	Surplus equipment cluttering the ward area
Equipment	Environmental Factor	Tubing Pinched	Adverse Major	Increased Probability of Failure	Tubing pinched in furniture or other equipment at the bed side
Equipment	Equipment Change-over	Patient Monitoring	Benign	Increased Probability of Failure	Mistakes or equipment failures when changing from portable to installed monitoring or vice-versa
Equipment	Equipment check	Normal Function	Adverse Minor	Increased Probability of Failure	Equipment improperly checked
Equipment	Equipment Failure	Accessory Failure	Adverse Minor	Increased Probability of Failure	Physical failure of a patient connected accessory
Equipment	Equipment Failure	Bed Fault	Adverse Major	Near Miss	Technical or physical failures of the bed or associated equipment
Equipment	Nurse Actions	Environmental Factor	Adverse Minor	Increased Probability of Failure	Interference from an environmental factor affecting a nurses actions in the use of equipment
Equipment	Nurse Actions	Environmental Factor	Benign	Increased Probability of Failure	Interference from an environmental factor affecting a nurses actions in the use of equipment
Equipment	Nurse Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to respond to an alarm or some other equipment issue
Equipment	Patient Transfer	Communication Issues	Adverse Major	Increased Probability of Failure	Failure of staff to communicate

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					regarding equipment required in patient transfer
Equipment	Visitor Actions	Environmental Factor	Adverse Minor	Near Miss	Environmental issues like noise or cramped space cause visitors actions to interfere with the therapy
Monitoring	Doctor Actions	Patient Monitoring	Adverse Major	Increased Probability of Failure	Human error by clinical staff when monitoring patients
Monitoring	Equipment Disconnect	Patient Monitoring	Adverse Major	Increased Probability of Failure	Undetected disconnection of patient monitoring equipment
Monitoring	Equipment Disconnect	Patient Monitoring	Adverse Minor	Increased Probability of Failure	Undetected disconnection of patient monitoring equipment
Monitoring	Nurse Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to respond to or implement patient monitoring
Monitoring	Nurse Actions	Patient Monitoring	Adverse Minor	Increased Probability of Failure	Failure to respond to or implement patient monitoring
Monitoring	Patient Monitoring	Failure To Act	Adverse Minor	Increased Probability of Failure	Failure to respond to or implement patient monitoring
Monitoring	Nurse Actions	Patient Monitoring	Adverse Minor	Undetermined	Failure to respond to or implement patient monitoring
Monitoring	Nurse Actions	Lack of Staff	Adverse Minor	Increased Probability of Failure	Failure to respond to patient or therapy monitoring alerts due to a lack of staff
Monitoring	Patient Actions	Patient Monitoring	Adverse Minor	Increased Probability of Failure	Patient actions adversely affecting patient monitoring
Monitoring	Patient Disconnection	Accessory Displacement	Adverse Major	Aversion	Failure of patient or therapy monitoring to detect a patient disconnection
Monitoring	Patient Monitoring	Patient Entanglement	Adverse Minor	Increased Probability of Failure	Failure to detect patient entanglement in oxygen tubing

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Monitoring	Therapy Administration/Monitoring	Cylinder Depletion	Adverse Major	Near Miss	Failure to detect cylinder depletion when in use
Monitoring	Therapy Administration/Monitoring	Obscured View	Adverse Minor	Increased Probability of Failure	Environmental factor obscuring a clear view of the patient
Monitoring	Therapist Actions	Therapy Administration/Monitoring	Remedial Proactive	Aversion	Failure to adequately monitor a patient during treatment with another therapy
Monitoring	Failure To Act	Therapy Administration/Monitoring	Adverse Major	Near Miss	Failure to respond to or implement therapy monitoring
Monitoring	Nurse Actions	Patient Monitoring	Remedial Proactive	Aversion	Incorrect action when responding to or implementing patient monitoring
Monitoring	Nursing Tasks	Patient Monitoring	Benign	Increased Probability of Failure	Incorrect action when responding to or implementing patient monitoring
Monitoring	Nursing Tasks	Patient Monitoring	Remedial Proactive	Undetermined	Incorrect action when responding to or implementing patient monitoring
Monitoring	Patient Monitoring	Monitoring Error	Adverse Major	Increased Probability of Failure	Incorrect action when responding to or implementing patient monitoring
Monitoring	Patient Monitoring	Monitoring Error	Adverse Minor	Increased Probability of Failure	Incorrect action when responding to or implementing patient monitoring
Nursing Task	Patient Transfer	Patient Arrival	Benign	Undetermined	Process errors when patients arrive after transfer
Nursing Task	Nursing Tasks	Other Therapy	Adverse Minor	Discomfort	Administering or adjusting another therapy causes interference with this one
Nursing Task	Nursing Tasks	Other Therapy	Benign	Undetermined	Administering or adjusting another therapy causes

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					interference with this one
Nursing Task	Nursing Tasks	Other Therapy	Remedial Reactive	Undetermined	Administering or adjusting another therapy causes interference with this one
Nursing Task	Nursing Tasks	Other Therapy	Undetermined	Undetermined	Administering or adjusting another therapy causes interference with this one
Nursing Task	Patient Transfer	Bed space Move	Undetermined	Increased Probability of Failure	Process errors moving patients from one bed to another
Nursing Task	Environmental Factor	Patient Access	Adverse Minor	Increased Probability of Failure	Environmental factor obstructing access to the patient
Nursing Task	Nurse Actions	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Nursing Task	Nurse Actions	Accessory Displacement	Adverse Minor	Minor Injury/Slight Worsening	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Nursing Task	Nursing Tasks	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Nursing Task	Nurse Actions	Accessory Displacement	Benign	Increased Probability of Failure	Failure to notice an incorrectly positioned accessory
Nursing Task	Nurse Actions	Patient Posture/Position	Benign	Undetermined	Changing a patients posture or position interferes with the therapy
Nursing Task	Nursing Tasks	Patient Posture/Position	Benign	Increased Probability of Failure	Changing a patients posture or position interferes with the therapy
Nursing Task	Nurse Actions	Patient Transfer	Benign	Undetermined	Preparing a patient for transfer interferes with the therapy

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Nursing Task	Nursing Tasks	Patient Bed/Chair Transfer	Benign	Increased Probability of Failure	Moving a patient between bed and chair causes interference with the therapy
Nursing Task	Nursing Tasks	Patient Bed/Chair Transfer	Undetermined	Undetermined	Moving a patient between bed and chair causes interference with the therapy
Nursing Task	Nursing Tasks	Patient Condition	Undetermined	Undetermined	Incorrect action when responding to a change in a patients condition
Nursing Task	Nursing Tasks	Patient Hand-Over	Benign	Undetermined	Incorrect actions at patient handover
Nursing Task	Nursing Tasks	Patient Transfer	Benign	Increased Probability of Failure	Incorrect actions during patient transfer
Nursing Task	Nursing Tasks	Patient Transfer	Benign	Undetermined	Incorrect actions during patient transfer
Nursing Task	Nursing Tasks	Patient Transfer	Undetermined	Undetermined	Incorrect actions during patient transfer
Nursing Task	Patient Transfer	Normal Function	Undetermined	Undetermined	Incorrect actions during patient transfer
Nursing Task	Therapy Administration/Monitoring	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to act on a detected therapy administration error
Nursing Task	Therapy Administration/Monitoring	Therapy Stopped	Adverse Minor	Increased Probability of Failure	Failure to detect that the therapy has terminated early
Nursing Task	Therapy Administration/Monitoring	Therapy Stopped	Benign	Increased Probability of Failure	Failure to act on a detected early therapy termination
Nursing Task	Nurse Actions	Nursing Tasks	Adverse Minor	Discomfort	General nursing tasks interfering with the therapy
Nursing Task	Nurse Actions	Nursing Tasks	Benign	Undetermined	General nursing tasks interfering with the therapy
Nursing Task	Nurse Actions	Patient Care	Benign	Undetermined	General nursing tasks interfering with the therapy
Nursing Task	Nursing Tasks	Bed sheets changed	Benign	Next Event Trigger	General nursing tasks interfering with the therapy
Nursing Task	Nursing Tasks	Nature Calls	Benign	Discomfort	General nursing tasks

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					interfering with the therapy
Other Therapy	Clinical Actions	Other Therapy	Adverse Minor	Discomfort	Administering or adjusting another therapy causes interference with this one
Other Therapy	Clinical Actions	Other Therapy	Adverse Minor	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Nurse Actions	Medication	Benign	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Nursing Tasks	Other Therapy	Benign	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Nursing Tasks	Other Therapy	Undetermined	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Other Therapy	Medication	Adverse Minor	Discomfort	Administering or adjusting another therapy causes interference with this one
Other Therapy	Therapist Actions	Other Therapy	Benign	Discomfort	Administering or adjusting another therapy causes interference with this one
Other Therapy	Therapist Actions	Other Therapy	Benign	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Therapy Started	Other Therapy	Remedial Other	Undetermined	Administering or adjusting another therapy causes interference with this one
Other Therapy	Equipment Failure	Other Therapy	Adverse Major	Discomfort	Equipment delivering another therapy fails causing interference with this one
Other Therapy	Human Factors	Distraction	Adverse Minor	Increased Probability of Failure	A required action related to another therapy causes a distraction which compromises

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					this therapy
Other Therapy	Patient Actions	Other Therapy	Adverse Major	Near Miss	A patient takes action related to another therapy, which compromises this one
Patient Action	Patient Actions	Medication	Adverse Minor	Discomfort	A patient takes action related to another therapy, which compromises this one
Patient Action	Accessory Displacement	Patient Actions	Adverse Minor	Undetermined	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Major	Increased Probability of Failure	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Major	Next Event Trigger	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Major	Undetermined	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Minor	Discomfort	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Accessory Displacement	Adverse Minor	Undetermined	Accessory moved into an incorrect position by Patient
Patient Action	Patient Actions	Confused Thrashing	Adverse Minor	Increased Probability of Failure	Unintentional action by patient interferes with the therapy
Patient Action	Patient Actions	Inappropriate Action	Adverse Major	Undetermined	Unauthorized or inappropriate action by the patient
Patient Action	Patient Actions	Nature Calls	Adverse Minor	Increased Probability of Failure	Action taken by a patient related to natural relief compromises the therapy
Patient Action	Patient Actions	Patient Comfort	Adverse Minor	Discomfort	Action taken by a patient to relieve discomfort

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					compromises the therapy
Patient Action	Patient Actions	Patient Comfort	Benign	Next Event Trigger	Action taken by a patient to relieve discomfort compromises the therapy
Patient Action	Patient Actions	Patient Co-operation	Adverse Major	Increased Probability of Failure	Patient refuses to co-operate with clinical staff regarding the therapy
Patient Action	Patient Actions	Patient Co-operation	Adverse Minor	Undetermined	Patient refuses to co-operate with clinical staff regarding the therapy
Patient Action	Patient Co-operation	Failure To Act	Adverse Minor	Increased Probability of Failure	Patient refuses to co-operate with clinical staff regarding the therapy
Patient Action	Patient Actions	Patient Eating/Drinking	Benign	Increased Probability of Failure	Patient has to take action to enable them to eat or drink which compromises the therapy
Patient Action	Patient Actions	Patient Eating/Drinking	Benign	Undetermined	Patient has to take action to enable them to eat or drink which compromises the therapy
Patient Action	Patient Actions	Patient Entanglement	Adverse Minor	Increased Probability of Failure	Actions by patient causes them to become entangled in the oxygen tubing
Patient Action	Patient Actions	Patient Monitoring	Adverse Minor	Increased Probability of Failure	Actions by the patient interfere with the patient monitoring
Patient Action	Patient Actions	Patient Posture/Position	Adverse Minor	Increased Probability of Failure	Actions by the patient to change position or posture interfere with the therapy
Patient Action	Patient Actions	Patient Sleeping	Benign	Increased Probability of Failure	Movements or actions during sleep compromise the therapy
Patient Action	Patient Actions	Patient Sleeping	Benign	Undetermined	Movements or actions during sleep compromise the therapy
Patient Action	Patient Actions	Patient Talking	Benign	Increased Probability of Failure	Actions taken by patient to allow them to talk

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					compromises the therapy
Patient Action	Patient Actions	Patient Talking	Benign	Undetermined	Actions taken by patient to allow them to talk compromises the therapy
Patient Action	First Contact	Patient Actions	Adverse Minor	Increased Probability of Failure	Innocent action by patient compromises the therapy
Patient Action	Patient Actions	Tampering	Adverse Minor	Increased Probability of Failure	A patient tampers with their therapy
Patient Action	Patient Co-operation	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Patient refuses to co-operate with the therapy by removing the accessory
Patient Action	Patient Eating/Drinking	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Patient has to take action to enable them to eat or drink which compromises the therapy
Patient Action	Patient Actions	Patient Safety	Adverse Minor	Increased Probability of Failure	Purposeful action by patient compromises the therapy
Patient Comfort	Nursing Tasks	Patient Posture/Position	Remedial Other	Undetermined	Changing a patients posture or position interferes with the therapy
Patient Comfort	Human Factors	Patient Comfort	Adverse Minor	Discomfort	Some aspect of the therapy causes discomfort
Patient Comfort	Patient Actions	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Patient displaces accessory because it is causing discomfort
Patient Comfort	Patient Comfort	Nature Calls	Adverse Minor	Next Event Trigger	Action taken by nursing staff to aid a patient to obtain natural relief compromises the therapy
Patient Comfort	Therapy Adjustment	Accessory Change	Remedial Reactive	Aversion	The accessory has to be changed to relieve patient discomfort
Patient Comfort	Patient Co-operation	Nursing Tasks	Adverse Minor	Discomfort	Lack of co-operation by patient regarding a nursing task causes therapy to become uncomfortable

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Patient Comfort	Patient Transfer	Patient Bed/Chair Transfer	Benign	Undetermined	Moving patient between bed and chair causes the therapy to become uncomfortable
Patient Condition	Nurse Actions	Accessory Displacement	Remedial Reactive	Aversion	Failure to notice an incorrectly positioned accessory
Patient Condition	Nursing Tasks	Patient Care	Remedial Reactive	Undetermined	Incorrect action when responding to a change in a patients condition
Patient Condition	Patient Actions	Patient Condition	Adverse Minor	Increased Probability of Failure	Incorrect action when responding to a change in a patients condition
Patient Condition	Patient Condition		Adverse Major	Undetermined	Incorrect action when responding to a change in a patients condition
Patient Condition	Communication Issues	Patient Condition	Adverse Minor	Increased Probability of Failure	The patients condition minimises communication
Patient Condition	Nurse Actions	Therapy Started	Remedial Reactive	Aversion	Undetected change in patient condition
Patient Condition	Patient Safety	Patient Condition	Adverse Major	Increased Probability of Failure	Undetected change in patient condition
Patient Condition	Patient Condition	Nausea or Vomiting	Adverse Minor	Discomfort	Patient vomiting while an accessory is in position
Patient Condition	Patient Condition	Nausea or Vomiting	Adverse Minor	Increased Probability of Failure	Patient vomiting while an accessory is in position
Patient Condition	Patient Condition	Nausea or Vomiting	Adverse Minor	Undetermined	Patient vomiting while an accessory is in position
Patient Condition	Patient Condition	Patient Confusion	Adverse Minor	Increased Probability of Failure	Inability for patient to co-operate interferes with the therapy
Patient Safety	Researcher Actions		Remedial Reactive	Undetermined	Failure to recognize and act on an imminent therapy failure
Patient Safety	Procedural	Prescription	Adverse Minor	Increased Probability of Failure	Prescriptions or treatment orders incorrect or not made

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Patient Safety	Nurse Actions	Patient Posture/Position	Remedial Proactive	Aversion	Changing a patients posture or position interferes with the therapy
Patient Safety	Patient Actions	Other Therapy	Adverse Minor	Undetermined	A patient takes action related to another therapy, which compromises this one
Patient Safety	Environmental Factor	Human Factors	Adverse Minor	Near Miss	Environmental factor masks information relating to a change in patient condition
Patient Safety	Human Factors	Distraction	Adverse Minor	Increased Probability of Failure	A factor relating to design within the therapy or the environment causes staff to be distracted
Patient Safety	Patient Safety	Procedural	Adverse Minor	Undetermined	A latent error in a defined procedure causes mistakes
Resources	Environmental Factor	Equipment Missing/Unavailable	Adverse Major	Increased Probability of Failure	A lack of available equipment for therapy administration or monitoring
Resources	Organisational Factor	Lack of Staff	Adverse Major	Increased Probability of Failure	Insufficient staff numbers to effectively manage patients receiving therapy
Therapy Setup	First Contact	Normal Function	Benign	Undetermined	Patients talking to visitors
Therapy Setup	Nursing Tasks	Medication	Adverse Minor	Discomfort	Administering or adjusting another therapy causes interference with this one
Therapy Setup	Therapy Administration/Monitoring	Cylinder Depletion	Adverse Major	Undetermined	Failure to detect cylinder depletion when in use
Therapy Setup	Accessory Displacement		Adverse Major	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Accessory Displacement		Adverse Minor	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					position by clinical staff
Therapy Setup	Nurse Actions	Accessory Adjustment	Remedial Proactive	Undetermined	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Nurse Actions	Accessory Adjustment	Remedial Reactive	Aversion	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Nurse Actions	Accessory Adjustment	Remedial Reactive	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Nurse Actions	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Therapy Administration/Monitoring	Accessory Adjustment	Remedial Reactive	Aversion	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Therapy Administration/Monitoring	Accessory Displacement	Adverse Major	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Therapy Administration/Monitoring	Accessory Displacement	Adverse Major	Undetermined	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Therapy Administration/Monitoring	Accessory Displacement	Adverse Minor	Increased Probability of Failure	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Therapy Administration/Monitoring	Accessory Displacement	Undetermined	Undetermined	Accessory incorrectly administered or moved into an incorrect position by clinical staff
Therapy Setup	Doctor Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to act on a detected therapy administration

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					error
Therapy Setup	Doctor Actions	Failure To Act	Adverse Minor	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Nurse Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Nurse Actions	Failure To Act	Adverse Major	Undetermined	Failure to act on a detected therapy administration error
Therapy Setup	Nurse Actions	Failure To Act	Adverse Minor	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Nurse Actions	Failure To Act	Adverse Minor	Undetermined	Failure to act on a detected therapy administration error
Therapy Setup	Therapist Actions	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Therapy Administration/Monitoring	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Therapy Administration/Monitoring	Failure To Act	Adverse Minor	Increased Probability of Failure	Failure to act on a detected therapy administration error
Therapy Setup	Accessory Displacement	Patient Talking	Adverse Minor	Undetermined	Actions taken by patient to allow them to talk compromises the therapy
Therapy Setup	Setup Error	Therapy Humidification	Adverse Major	Increased Probability of Failure	Humidifier incorrectly set up, used inappropriately or not used when it should
Therapy Setup	Accessory Displacement	Failure To Act	Adverse Major	Increased Probability of Failure	Failure to correct a displaced accessory
Therapy Setup	Failure To Act	Accessory Displacement	Adverse Major	Increased Probability of Failure	Failure to correct a displaced accessory
Therapy Setup	Doctor Actions	Therapy Discontinued	Undetermined	Undetermined	Therapy terminated early in error
Therapy Setup	Nurse Actions	Therapy Discontinued	Adverse Major	Minor Injury/Slight Worsening	Therapy terminated early in error
Therapy Setup	Nurse Actions	Therapy Discontinued	Benign	Undetermined	Therapy terminated

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					early in error
Therapy Setup	Nurse Actions	Therapy Discontinued	Undetermined	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Adjustment	Therapy Discontinued	Benign	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Adjustment	Therapy Discontinued	Remedial Reactive	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Adjustment	Therapy Discontinued	Undetermined	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Adjustment	Therapy Stopped	Adverse Major	Minor Injury/Slight Worsening	Therapy terminated early in error
Therapy Setup	Therapy Adjustment	Therapy Stopped	Adverse Minor	Increased Probability of Failure	Therapy terminated early in error
Therapy Setup	Therapy Administration/Monitoring	Therapy Stopped	Undetermined	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Discontinued	Normal Function	Benign	Undetermined	Therapy terminated early in error
Therapy Setup	Therapy Discontinued	Nursing Tasks	Benign	Undetermined	Therapy terminated early in error
Therapy Setup	First Contact	Accessory Displacement	Adverse Major	Increased Probability of Failure	failure to detect a displaced accessory
Therapy Setup	First Contact	Accessory Displacement	Adverse Major	Undetermined	failure to detect a displaced accessory
Therapy Setup	First Contact	Accessory Displacement	Adverse Minor	Increased Probability of Failure	failure to detect a displaced accessory
Therapy Setup	Human Factors	Setup Error	Adverse Major	Near Miss	A factor relating to design within the therapy or the environment causes setup error
Therapy Setup	Nurse Actions	Communication Issues	Adverse Major	Undetermined	Nursing staff failing to communicate effectively regarding a patient's therapy
Therapy Setup	Nurse Actions	Setup Error	Adverse Minor	Increased Probability of Failure	Mistakes in setting up the therapy
Therapy Setup	Nurse Actions	Supply Fail	Adverse Minor	Increased Probability of Failure	Failure to detect a failed oxygen supply
Therapy Setup	Nurse Actions	Therapy Administration/Monitoring	Remedial Reactive	Aversion	Incorrect action taken when attempting to rectify a setup error
Therapy Setup	Therapy Administration/Monitoring	Remedial Action	Remedial Reactive	Aversion	Incorrect action taken when attempting to rectify a setup error

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
Therapy Setup	Nurse Actions	Tubing Disconnect	Adverse Minor	Discomfort	Therapy tubing disconnected in error
Therapy Setup	Nursing Tasks	Accessory Displacement	Undetermined	Increased Probability of Failure	Accessory is displaced as a result of a general nursing task
Therapy Setup	Therapy Adjustment	Accessory Change	Adverse Major	Next Event Trigger	A change of accessory is incorrectly implemented
Therapy Setup	Therapy Adjustment	Accessory Change	Benign	Undetermined	A change of accessory is incorrectly implemented
Therapy Setup	Patient Co-operation	Failure To Act	Adverse Minor	Increased Probability of Failure	A patient compromises the therapy setup by not co-operating with staff
Therapy Setup	Patient Posture/Position	Accessory Displacement	Adverse Minor	Increased Probability of Failure	An accessory is displaced when a patient's position or posture is changed
Therapy Setup	Therapy Administration/Monitoring	Accessory Disconnect	Adverse Minor	Increased Probability of Failure	An accessory is incorrectly or inappropriately disconnected by clinical staff
Therapy Setup	Nursing Tasks	Therapy Administration/Monitoring	Remedial Proactive	Undetermined	An incorrect adjustment is made to the therapy
Therapy Setup	Therapist Actions	Therapy Adjustment	Undetermined	Undetermined	An incorrect adjustment is made to the therapy
Therapy Setup	Therapy Adjustment	Accessory Adjustment	Remedial Reactive	Undetermined	An incorrect adjustment is made to the therapy
Therapy Setup	Setup Error	Bubble Tubing	Adverse Minor	Undetermined	Bubble tubing incorrectly cut
Therapy Setup	Patient Transfer	Supply Change	Benign	Increased Probability of Failure	Change either way between piped supply and cylinder incorrectly implemented
Therapy Setup	Therapy Adjustment	Supply Change	Benign	Increased Probability of Failure	Change either way between piped supply and cylinder incorrectly implemented
Therapy Setup	Therapy Adjustment	Supply Change	Remedial Reactive	Aversion	Change either way between piped supply and cylinder incorrectly implemented
Therapy Setup	Therapy Adjustment	Supply Change	Undetermined	Increased Probability of Failure	Change either way between piped supply and cylinder

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					incorrectly implemented
Therapy Setup	Therapy Administration/Monitoring	Supply Change	Benign	Increased Probability of Failure	Change either way between piped supply and cylinder incorrectly implemented
Therapy Setup	Patient Disconnection	Therapy Administration/Monitoring	Adverse Major	Near Miss	Failure by clinical staff to detect a patient disconnection
Therapy Setup	Patient Disconnection	Therapy Administration/Monitoring	Adverse Major	Undetermined	Failure by clinical staff to detect a patient disconnection
Therapy Setup	Setup Error	Therapy Administration/Monitoring	Adverse Minor	Undetermined	Failure to detect a setup error
Therapy Setup	Therapy Adjustment	Therapy Flow Rate	Benign	Discomfort	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Adjustment	Therapy Flow Rate	Benign	Undetermined	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Adjustment	Therapy Flow Rate	Remedial Other	Undetermined	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Adjustment	Therapy Flow Rate	Remedial Reactive	Undetermined	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Administration/Monitoring	Therapy Flow Rate	Adverse Minor	Increased Probability of Failure	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Administration/Monitoring	Therapy Flow Rate	Undetermined	Undetermined	Flow rate incorrectly or inappropriately adjusted
Therapy Setup	Therapy Administration/Monitoring	Therapy Started	Remedial Reactive	Aversion	Therapy incorrectly or inappropriately set up when re-administered after a previous termination
Therapy Setup	Therapy Administration/Monitoring	Tubing Disconnect	Adverse Major	Increased Probability of Failure	Undetected accidental or erroneous tubing disconnection
Therapy Setup	Therapy Administration/Monitoring	Tubing Disconnect	Adverse Minor	Discomfort	Undetected accidental or erroneous tubing disconnection
Therapy Setup	Therapy Administration/Monitoring	Tubing Disconnect	Adverse Minor	Increased Probability of Failure	Undetected accidental or erroneous tubing disconnection
Therapy Setup	Therapy Administration/Monitoring	Tubing Disconnect	Undetermined	Undetermined	Undetected accidental or erroneous tubing

Type(Focus)	Category	Sub-Category	Event Class	Consequence	Hazardous Element
					disconnection
Therapy Setup	Therapy Administration/Monitoring	Therapy Humidification	Adverse Minor	Undetermined	Undetected humidifier water depletion
Therapy Setup	Setup Error	Accessory Choice Error	Adverse Major	Increased Probability of Failure	Wrong type of accessory used for a particular therapy setup
Therapy Setup	Therapy Administration/Monitoring	Setup Error	Adverse Minor	Undetermined	Therapy not set up according to prescription or treatment order

Appendix B ：The Questionnaire

B.1 The Questionnaire Layout

Questionnaire to assess the risk to patients on Oxygen Therapy

Introduction

This short questionnaire is an attempt to get an idea of how often clinical staff encounter problems with oxygen therapy, and what the main causes of the problems might be.

A problem is defined as any instance where oxygen therapy is the main cause of harm or “near miss” to a patient or anyone else. There may be clinical reasons, or it may be the result of therapy being interrupted, stopped or changed in some way that was unexpected or as a result of some failure or error. There may be instances where oxygen was not administered to the patient when it should have. Instances of falling cylinders or people becoming entangled in tubing and other physical problems should also be included.

Your involvement is entirely voluntary.

You will remain entirely anonymous; you **cannot** be identified from any of the information on this form. In order to further preserve your identity it is suggested that you refrain from discussing the questionnaire with your colleagues.

Please answer each question in turn, try not to read ahead or answer the questions out of sequence.

Please make use of the extra space provided for further information, even if it seems trivial. It is up to you to decide how involved your answers are; but the more information that can be gathered, the better the chances that the outcome of the research will benefit patient and staff safety.

Although the risks to some patients in the use of oxygen are known, there is very little data available on how often problems occur, or what all the hazards are. The information gathered from this questionnaire will be used along with other research to catalogue and quantify the risks in order to improve patient safety.

The research is conducted in collaboration between The Trust and Cranfield University. Please ask the researcher for further information if required.

Please return your completed questionnaire via internal mail to:

Marcus Durand

[Internal mail address for hospital site]

Thank you for your help in improving patient safety.

1. Which professional group best describes you?

Student Nurse	Qualified Nurse	Trainee Doctor	SAS Doctor	Consultant	Therapist	Technologist	CSW
☐	☐	☐	☐	☐	☐	☐	☐

Not listed? Please specify.

2. How many times have you *ever* seen <u>patients harmed or badly affected</u> in some way as a result of Oxygen Therapy?

Please write an approximate number here. ☐

It doesn't have to be exact your best estimate will do

If you would like to give some details please do so here. Continue on a separate sheet if needed.

3. In those instances where there have been problems with Oxygen Therapy, even if no-one has been harmed, what proportions were from the following causes?

A. Empty Cylinders

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

B. Patient actions e.g. removing mask or pulling tubing off flow meter.

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

C. Faults with tubing, masks or nasal specs

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

D. Incorrect or unreadable notes or prescriptions

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

E. Faulty wall supply

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

F. Actions of others, (e.g. Visitors, Therapists, Cleaners, etc.)

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

G. Set-up errors

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

H. Faulty regulator or flow meter

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

I. Incorrect prescription

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

J. Other causes. Please describe the cause:

☐

None ☐ Very few ☐ Few ☐ Many ☐ Most ☐ All ☐

4. Approximately how many instances, even where no-one was harmed, have you seen in the last *12 months* where there have been problems with Oxygen Therapy?

Please write an approximate number here.

If you would like to give some details please do so here. Continue on a separate sheet if needed.

5. Do you think current guidelines are adequate in ensuring patient safety during Oxygen Therapy?

Not at all ☐ Poorly ☐ Partly ☐ Adequately ☐ Mainly ☐ Completely ☐

If you would like to give some further comments please do so here. Continue on a separate sheet if needed.

6. When did you start working in healthcare? Please include your time as a trainee.

Day / Month / Year

B.2 The proportional frequency ranking of causes from question 3

In Table Appendix B.2-1, the themes are listed on the left with the frequency choices along the top. The choices per frequency are shown in the resulting matrix. 1656 choices were made in total.

Table Appendix B.2-1 Responses to Question three.

	All	Most	Many	Few	V Few	None
Patient Actions	4	18	58	56	24	24
Other	2	3	3	9	5	0
Prescription	1	4	9	22	37	105
Empty Cylinders	0	5	14	38	44	78
Accessories	0	0	3	25	57	98
Notes	0	1	17	29	40	95
Wall Supply	0	0	1	25	31	125
Other's Actions	0	2	0	25	45	111
Set-Up	0	1	7	34	52	88
Reg or Flow	0	0	4	26	57	94

The proportion of choices was calculated by dividing the value in each cell by the total number of choices, resulting in the matrix of Table Appendix B.2-2.

Table Appendix B.2-2 Choices Proportional to Total.

	All	Most	Many	Few	V Few	None
Patient Actions	0.0024	0.0109	0.0350	0.0338	0.0145	0.0145
Other	0.0012	0.0018	0.0018	0.0054	0.0030	0.0000
Prescription	0.0006	0.0024	0.0054	0.0133	0.0223	0.0634
Empty Cylinders	0.0000	0.0030	0.0085	0.0229	0.0266	0.0471
Accessories	0.0000	0.0000	0.0018	0.0151	0.0344	0.0592
Notes	0.0000	0.0006	0.0103	0.0175	0.0242	0.0574
Wall Supply	0.0000	0.0000	0.0006	0.0151	0.0187	0.0755
Other's Actions	0.0000	0.0012	0.0000	0.0151	0.0272	0.0670
Set-Up	0.0000	0.0006	0.0042	0.0205	0.0314	0.0531
Reg or Flow	0.0000	0.0000	0.0024	0.0157	0.0344	0.0568

The value in each cell of Table Appendix B.2-2 was multiplied by the weighting score for each choice, as in the final matrix of Table Appendix B.2-3.

Table Appendix B.2-3 Proportional Scores for Each Theme and Frequency Choice.

Weighting Scores	5	4	3	2	1	0
	All	Most	Many	Few	V Few	None
Patient Actions	0.0121	0.0435	0.1051	0.0676	0.0145	0.0000
Other	0.0060	0.0072	0.0054	0.0109	0.0030	0.0000
Prescription	0.0030	0.0097	0.0163	0.0266	0.0223	0.0000
Empty Cylinders	0.0000	0.0121	0.0254	0.0459	0.0266	0.0000
Accessories	0.0000	0.0000	0.0054	0.0302	0.0344	0.0000
Notes	0.0000	0.0024	0.0308	0.0350	0.0242	0.0000
Wall Supply	0.0000	0.0000	0.0018	0.0302	0.0187	0.0000
Other's Actions	0.0000	0.0048	0.0000	0.0302	0.0272	0.0000
Set-Up	0.0000	0.0024	0.0127	0.0411	0.0314	0.0000
Reg or Flow	0.0000	0.0000	0.0072	0.0314	0.0344	0.0000

The scores for each theme were added together and then sorted to provide the ranked list in Table Appendix B.2-4.

Table Appendix B.2-4 Final Ranked Scores.

Themes	Total Scores
Patient Actions	0.2428
Empty Cylinders	0.1099
Notes	0.0924
Set-Up	0.0876
Prescription	0.0779
Reg or Flow	0.0731
Accessories	0.0700
Other's Actions	0.0622
Wall Supply	0.0507
Other	0.0326

Appendix C The Observations and Questionnaire Hazard Analysis

C.1 The Observations and Questionnaire Combined Hazard Analysis

Table Appendix C.1-1 The Observations and Questionnaire Combined Hazard Analysis.

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
1	Incorrect clinical decision or action	Undetected incorrect clinical decision or action	Incorrect information, lack of knowledge or skill, human error	Incorrect, Inadequate or No Therapy
2	Failure to recognize and act on an imminent therapy failure	Undetected therapy failure	Lack of vigilance, knowledge or Skill	Incorrect, Inadequate or No Therapy
3	Unauthorized or inappropriate action by others	Incorrect action by an unauthorized person	Unrestricted access to the therapy	Incorrect, Inadequate or No Therapy, discomfort, physical harm
4	An environmental factor promotes inappropriate action	Undertaking tasks in an environment of excessive Noise, Light, Darkness or discomfort	An environment of excessive Noise, Light, Darkness or discomfort	Incorrect, Inadequate or No Therapy, discomfort, physical harm
5	Non clinical staff rectifying an environmental fault	Unexpected events due to non clinical maintenance work	Failure of an environmental control mechanism	Unexpected and unpredictable influence on therapy
6	Distraction caused by activity on the ward	Distraction of clinical staff	Unusual or intrusive activity on the ward	Impaired vigilance, Increased possibility of human error
7	Latent error causes a failure in communication or process	Latent error in communication or process methods	Communication or process failure	Following the usual process leads to error
8	Patient management errors when patients arrive after transfer	Patient Management error	Patient arrival on the ward	Patient placed in an incorrect ward or bed space resulting in inadequate, unreliable or no therapy
9	Inadequacy of pro forma or another communication tool	Missing or incorrect information	An inadequate communication tool	Delays or incorrect decisions based on poor information
10	Innocent action by visitor to aid patient comfort compromises this therapy	Incorrect action by an unauthorized person	Therapy parameters are changed by uninformed action by visitor when patient or equipment is moved	Reduced or interrupted therapy or no therapy if undetected. Distracted staff.
11	Patients talking to visitors	Suspension of therapy	Patients need to talk, eat or leave the bed	Increased possibility of therapy not being resumed
12	Visitors tampering with therapies	Incorrect action by an unauthorized person	Inappropriate adjustment or termination of therapy by visitors.	Reduced or interrupted therapy or no therapy if undetected, distracted staff
13	Clinical activity interfering with the therapy	Poorly considered clinical interventions to patient receiving oxygen therapy	Nursing or clinical tasks	Unexpected influence on therapy by routine tasks. Change induces ineffective therapy.

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
14	Administering or adjusting another therapy causes interference with this one	Undetected interference with oxygen therapy	Administration or changes in another therapy	Physical interference causing inadequate therapy
15	Wrong type of accessory used for a particular therapy setup	Wrong accessory for purpose	Human error, lack of knowledge/skill	Incorrect or inadequate therapy, discomfort, physical harm
18	Process or patient management errors moving patients from one bed to another	Patient placed in an inadequate bed space	Moving patients between bed spaces	Inadequate, incorrect or no therapy applied
20	Calls for assistance unanswered	Unanswered calls for assistance	Lack of vigilance	Incorrect, Inadequate or No Therapy, discomfort, physical harm
21	Patient requests or needs unfulfilled	Unfulfilled patient need	Failure to act	Incorrect, Inadequate or No Therapy, discomfort, physical harm
22	Impaired speech due to the face mask or other aspect of the therapy making communication difficult	Lack of communication through impaired speech	A face mask or other aspect of the therapy causing impairment	Limited communication
23	Communication failures at patient hand-over	Communication failure	Poor communication at patient handover	Incorrect action or failure to act
24	Missing or incomplete patient notes	Lack of information	Missing or incomplete patient notes	Delays or incorrect decisions based on poor information
25	Incorrect information in patient notes	Incorrect information	Incorrect information entered into patient notes	Incorrect action or failure to act
26	Poor communication between doctors and nursing staff	Communication failure between clinical staff	Poor communication between doctors and nursing staff	No therapy or incorrect therapy
27	Environmental factors such as noise masking calls for assistance	Unanswered calls for assistance	High levels of ambient noise	Impaired vigilance, No response to alarms from monitoring equipment and nurse calls
28	Communication failures between clinician and patient during an examination	Incorrect or incomplete information or diagnosis	Misunderstanding between doctor and patient	Incorrect or inadequate therapy, discomfort, physical harm
29	Nursing staff not responding to requests or orders from doctors	Communication failure between clinical staff	Communication or protocol failure	Incorrect action or failure to act
30	Prescriptions or treatment orders incorrect or not made	Incorrect action	Protocol or procedure failure	No therapy or incorrect therapy
31	Spectacles or other obstructions on the face	Poorly fitting patient accessory	Spectacles or other obstructions on the face	Incorrect or inadequate therapy, discomfort, physical harm
32	Position of cylinder at the bed side causes Physical obstruction	Physical obstruction at the bed side	Badly positioned Cylinder	Delayed or impaired access to patient, physical harm

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
32.1	Position of cylinder at the bed side causes unknown cylinder contents	Unknown cylinder contents	Obscured view of cylinder	Unreliable therapy, undetected cylinder depletion
32.2	Position of cylinders at the bed side causes patients movements to be restricted by tubing position	Patients movements restricted by tubing position	Cylinder too far from patient	Displaced accessory, discomfort
33	Surplus equipment cluttering the ward area	Obstructed access or confusion	Cluttered ward area	Ineffective equipment management, Physical obstructions, Reduced access, Confusion between used and full cylinders
34	Tubing pinched in furniture or other equipment at the bed side	Damaged or occluded tubing	Poor tubing position	Possible undetected tubing disconnection, occlusion or cutting causing a loss or reduction of therapy or an oxygen leak.
35	Mistakes or equipment failures when changing from portable to installed monitoring or vice-versa	Ineffective patient monitoring	Human error or equipment failure when changing between monitoring devices	delayed or ineffective monitoring
36	Equipment improperly checked	Unreliable equipment	Human error: Equipment checks	Unreliable therapy or monitoring
37	Physical failure of a patient connected accessory	Undetected accessory failure	Any physical or functional failure of any accessory	Limited or complete lack of therapy
38	Technical or physical failures of the bed or associated equipment	Malfunctioning bed or associated equipment	Equipment failure	Disturbance of therapy, distracted staff
39	Interference from an environmental factor affecting a nurses actions in the use of equipment	Equipment use error	Interference from an environmental factor	Therapy set up or monitoring errors
40	Failure to respond to an equipment alarm or warning	Undetected therapy failure	Lack of vigilance through unattended alarms or equipment notifications	Incorrect or inadequate therapy, discomfort, physical harm
41	Failure of staff to communicate regarding equipment required in patient transfer	Unavailable equipment	Failure to communicate a requirement	Incorrect or inadequate therapy, discomfort, physical harm
42	Environmental issues like noise or cramped space cause visitors actions to interfere with the therapy	Interference/tampering with the therapy	Visitors actions when reacting to the environment	Incorrect or inadequate therapy, discomfort, physical harm, distraction of staff
43	Human error by clinical staff when monitoring patients	Undetected therapy failure	Lack of vigilance through patient monitoring error	Incorrect or inadequate therapy, discomfort, physical harm

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
44	Undetected disconnection of patient monitoring equipment	Undetected monitoring failure	Monitoring equipment disconnection	Patient monitoring error, Incorrect or inadequate therapy, discomfort, physical harm
45	Failure to respond to or implement patient monitoring	Undetected therapy failure	Patient monitoring error through failure to act	Incorrect or inadequate therapy, discomfort, physical harm
46	Failure to respond to patient or therapy monitoring alerts due to a lack of staff	No response to monitoring alerts	lack of staff	Incorrect or inadequate therapy, discomfort, physical harm
47	Patient actions adversely affecting patient monitoring	Interference with patient monitoring	Patients actions	Ineffective patient monitoring
48	Failure of patient or therapy monitoring to detect a therapy disconnection	Undetected therapy disconnection	Ineffective patient monitoring	No therapy
49	Failure to detect patient entanglement in oxygen tubing	Undetected patient entanglement	Lack of vigilance	Impaired therapy, physical harm
50	Failure to detect cylinder depletion when in use	Undetected cylinder depletion	Lack of vigilance or information	No therapy
51	Environmental factor obscuring a clear view of the patient	Obscured view of patient	Environmental factor	Reduced patient monitoring, Impaired vigilance
52	Environmental factor obstructing access to the patient	Obstructed access to patient	Environmental factor	Delays, Reduced task capabilities, Physical harm
53	Accessory incorrectly administered or moved into an incorrect position by clinical staff	Misplaced accessory	Staff actions	Incorrect or inadequate therapy, discomfort, physical harm
54	Failure to notice an incorrectly positioned accessory	Misplaced accessory	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm
55	Changing a patients posture or position interferes with the therapy	Interference with the therapy	Change in patients posture or position	Incorrect or inadequate therapy, discomfort, physical harm
56	Preparing a patient for transfer interferes with the therapy	Interference with the therapy	Preparation for transfer	Incorrect or inadequate therapy, discomfort, physical harm
57	Moving a patient between bed and chair causes interference with the therapy	Interference with the therapy	Transferring a patient between bed and chair	Incorrect or inadequate therapy, discomfort, physical harm
58	Incorrect action when responding to a change in a patients condition	Clinical error: incorrect action	Change in patients condition	Incorrect or inadequate therapy, discomfort, physical harm
59	Incorrect actions at patient handover	Protocol/procedure error: Incorrect action	Handing over care from one team to another	Incorrect or inadequate therapy, discomfort, physical harm
60	Incorrect actions during patient transfer	Protocol/procedure error: Incorrect action	Transferring a patient between wards/departments	Incorrect or inadequate therapy, discomfort, physical harm

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
61	Failure to act on a detected therapy administration error	Failure to act on a Therapy administration error	Human error	Incorrect or inadequate therapy, discomfort, physical harm
62	Failure to detect that the therapy has terminated early	Undetected therapy termination	Therapy monitoring	No therapy, discomfort, physical harm
63	Failure to act on a detected early therapy termination	Failure to act on an early therapy termination	Human error	No therapy, discomfort, physical harm
64	Equipment delivering another therapy fails causing interference with this one	Interference with the therapy	Equipment Failure for another therapy	Incorrect or inadequate therapy, discomfort, physical harm
65	A required action related to another therapy causes a distraction which compromises this therapy	Staff distraction	Action required for the administration of another therapy	lack of vigilance, incomplete, Incorrect or inadequate therapy, discomfort, physical harm
66	A patient takes action related to another therapy, which compromises this one	Undetected therapy failure	Patients actions related to another therapy	Incorrect or inadequate therapy, discomfort, physical harm
67	Accessory moved into an incorrect position by Patient	Misplaced accessory	Patients actions	Incorrect or inadequate therapy, discomfort, physical harm
68	Unintentional action by patient interferes with the therapy	Undetected therapy failure	Patients actions	Incorrect or inadequate therapy, discomfort, physical harm
69	Unauthorized or inappropriate action by the patient	Undetected therapy failure	Unauthorized or inappropriate action by the patient	Incorrect or inadequate therapy, discomfort, physical harm
70	Action taken by a patient related to natural relief compromises the therapy	Suspension of therapy	Patient leaves the bed to go to the toilet	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff
71	Action taken by a patient to relieve discomfort compromises the therapy	Suspension of therapy	Patient changes position or moves between bed and chair	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff
72	Patient refuses to co-operate with clinical staff regarding the therapy	Suspension of therapy	Lack of patient co-operation	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff
73	Patient has to take action to enable them to talk, eat or drink	Suspension of therapy or food/drink not consumed	Patient has to suspend the therapy to enable them to talk, eat or drink	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, Food / drink not consumed, distracted staff

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
73.1	Patient has to take action to enable them to take oral meds	Suspension of therapy or oral meds not taken	Patient has to suspend the therapy to enable them to take oral meds	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, Oral meds not taken, distracted staff
74	Actions by patient causes them to become entangled in the oxygen tubing	Patient entanglement	Patient movements	Incorrect or inadequate therapy, discomfort, physical harm
75	Actions by the patient interfere with the patient monitoring	Patient monitoring interference	Patients actions or movements	Reduced patient monitoring, Impaired vigilance, staff distraction
77	Movements or actions during sleep compromise the therapy	Undetected therapy failure	Unintentional patient actions or movements	Interrupted therapy resulting in no therapy if this remains undetected
80	Innocent action by patient compromises the therapy	Undetected therapy failure	Unintentional	Interrupted therapy resulting in no therapy if this remains undetected
82	Patient refuses to co-operate with the therapy by removing and ignoring requests to replace the accessory	Misplaced accessory	Patient co-operation	Limited or no therapy and distracted staff
90	The accessory has to be changed to relieve patient discomfort	Misplaced accessory	Accessory causes discomfort	Patient removes accessory to relieve discomfort
91	The patients condition minimises communication and involvement	Limited information, patient involvement and feedback	Lack of communication	Patient cannot report changes in condition or requirement leading to the possibility for sub-optimal therapy
92	Undetected change in patient condition	Undetected change in patient condition	Lack of vigilance, ineffective patient monitoring, interference from an environmental factor	Incorrect or inadequate therapy, discomfort, physical harm
93	Patient vomiting while an accessory is in position	Choking	Vomiting into a face mask	If the patient is wearing a face mask, there is a strong possibility of choking. The mask has to be removed while the patient is vomiting, resulting in reduced or no therapy.
96	A factor relating to design within the therapy or the environment causes staff to be distracted	Distracted or inattentive staff	Human factors: Difficulty in administering therapy	Incorrect or inadequate therapy, discomfort, physical harm
97	A latent error in a defined procedure causes mistakes	Latent error in a procedure	Incorrectly defined procedure	Incorrect or inadequate therapy, discomfort, physical harm

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
98	Humidifier incorrectly set up, used inappropriately or not used when it should	Humidification error	Lack of procedure/protocol, Lack of knowledge/skill, Human factors, Lack of equipment	Incorrect or inadequate therapy, discomfort, physical harm
99	A lack of available equipment for therapy administration or monitoring	Lack of Equipment	Management error, Purchasing/stores error	Sub-optimal or ineffective therapy, No therapy
100	Insufficient staff numbers to effectively manage patients receiving therapy	Lack of staff	Management error, Institutional issue	Sub-optimal patient care, Reduced patient monitoring, Impaired vigilance, Inconsistent patient care, Inappropriate action, inadequate or no therapy
101	Failure to correct a displaced accessory	Misplaced accessory	Failure to act	Incorrect or inadequate therapy, discomfort, physical harm
105	A factor relating to design within the therapy or the environment causes setup error	Undetected setup error	Human factors: Difficulty in administering therapy	Incorrect or inadequate therapy, discomfort, physical harm
107	Mistakes in setting up the therapy	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm
108	Undetected failed oxygen supply	Undetected supply failure	Lack of vigilance and Wall port failure, flowmeter fault, Pipeline and alarm system failure or cylinder depletion	Incorrect or inadequate therapy, discomfort, physical harm
109	Incorrect action taken when attempting to rectify a setup error	Incorrect action	Setup error and human error	Incorrect or inadequate therapy, discomfort, physical harm
110	Therapy tubing disconnected in error	Undetected tubing disconnection	Inappropriate or inadvertent action	No therapy
113	A change of accessory is incorrectly implemented	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm
115	An accessory is displaced when a patient's position or posture is changed	Accessory displacement	Changing a patients posture or position	Incorrect or inadequate therapy, discomfort, physical harm
116	An accessory is incorrectly or inappropriately disconnected by clinical staff	Undetected accessory disconnection	Human error, Lack of Knowledge or Skill	Incorrect or inadequate therapy, discomfort, physical harm
117	An incorrect adjustment is made to the therapy	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm
118	Bubble tubing incorrectly cut	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
119	Change either way between piped supply and cylinder incorrectly implemented	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm
120	Failure by clinical staff to notice a patient disconnection	Undetected therapy disconnection	Lack of vigilance	No therapy
121	Failure to detect a setup error	Undetected setup error	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm
122	Flow rate incorrectly or inappropriately adjusted	Dosage error	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm
123	Therapy incorrectly or inappropriately set up when re-administered after a previous termination	Undetected incorrect or inappropriate therapy re-administration	Re-administering the therapy after a previous termination	Incorrect or inadequate therapy, discomfort, physical harm
125	Undetected humidifier water depletion	Undetected humidifier water depletion	Lack of vigilance	Inadequate, unreliable or no therapy
126	Wrong type of accessory used for a particular therapy setup	Use error	Lack of Knowledge or Skill	Limited, interrupted, Incorrect or No Therapy
127	Failure to adequately monitor a patient during treatment with another therapy	Undetected change in patient condition	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm
128	Patient requirement incorrectly assessed	clinical error: diagnosis/assessment	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm
129	Failure to respond to or implement therapy monitoring	Undetected therapy failure	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm
131	Incorrect action when responding to or implementing patient monitoring	Incorrect action	Human error, Lack of Knowledge / Skill	Reduced patient monitoring, Impaired vigilance, Incorrect or inadequate therapy, discomfort, physical harm
134	Other medication interfering with this therapy	Undetected drug interference	Communication error, Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm
136	Therapy not set up according to prescription or treatment order	Undetected setup error	Communication error, Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm
137	A human factors issue with any equipment causes a functional failure because Equipment is applied differently to its intended use	Incorrect application of equipment	Equipment use error	Limited, interrupted, Incorrect or No Therapy
139	Bed spaces are in close proximity	Confusion with therapies common to two patients in close proximity	Proximity of bed spaces, Poor ward layout, Patient management error, Ward management error, Central bed	Reduced access, Increased possibility of wrong patient incidents (e.g. wrong patients flow rate adjusted)

Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threat/Effect
			management error	
140	Two or more patients sharing a wall port or cylinder	Confusion with therapies common to two patients in close proximity	Shared resources, Human error, Ward layout error, Patient management error	Increased possibility of wrong patient incidents (e.g. wrong patients flow rate adjusted), Faster cylinder depletion, Possible common failure (same failure affecting two patients)
141	Sensitive alarms and persistent nurse calls from patients	Undetected therapy failure	Frequently occurring alarms	Desensitization to alarms resulting in Impaired vigilance, No response to alarms from monitoring equipment and nurse calls
143	Staff are allowed to undertake tasks without adequate or relevant skills or knowledge	No method available to prevent unauthorized staff attempting clinical or nursing tasks	Lack of skill/knowledge, protocol / procedure error	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy
145	No provision for the safe and organized storage of oxygen cylinders	The chaotic storage of used and full cylinders together	Inadequate Storage	Full and used cylinders stored together on the wards leading to the increased possibility of selecting one without adequate content
146	Lifts are shared with all building users	Extended and unpredictable transfer times	No dedicated lift Access for patient transfers	Prolonged patient transfers leading to an increased possibility of cylinder depletion, increased possibility of lifts failing and of physical harm to other lift users
147	Not enough oxygen outlets for the number of patients requiring therapy	Unavailability of piped oxygen outlets	Insufficient number of oxygen outlets	Cylinders have to be used, reducing the reliability of the therapy, or patients must be moved to other wards. Major threats are: Inadequate, unreliable or no therapy due to insufficient capacity.

Appendix D The Review of Incident Reports

D.1 Summary report from the NPSA

NHS

National Patient Safety Agency

Risks to patients on oxygen therapy

Review of data from the National Reporting and Learning System (NRLS)

Author: Dagmar Luettel **Date:** 30th March 2006

NRLS Reports Disclaimer Statement

The incidents summarised in this report have been drawn from the NPSA National Reporting and Learning System (NRLS). The NRLS supports the goal of the NPSA to make patient care safer. These incidents have been reported to the NRLS by NHS organisations across England and Wales. The NRLS is a confidential reporting system. The incidents are reported through a variety of routes, by individual NHS staff, including through local trust risk management systems and web based e-forms (including an open access e-form). The individual reports are not investigated or verified by the NPSA. Since these incidents are self-reported they are not necessarily representative of the NHS across England and Wales and therefore need interpreting with care.

For internal use only:

Permission must be obtained from the NPSA before the information contained within the report it is published or passed on to a third party outside the NPSA. For help with interpretation please contact the statistics team on DataRequestTeam@npsa.nhs.uk

1. Background & Purpose

This note summarises the review on incidents from the NRLS, which are related to oxygen therapy. The review has been undertaken following an external request. The objective of the analysis is to get a better understanding of what types of incidents are reported to the National Reporting and Learning System (NRLS) relating to oxygen therapy in acute/general hospitals.

2. Overview of analysis

A search of the NRLS database was carried out using the following search criteria:

- The search was performed for the time 24th November 2003 to 24th March 2006
- The search was limited to incidents, which occurred in acute/general hospitals
- A SAS autonomy search was performed in the NRLS database using the keywords 'oxygen' and 'O2'

3. Results

A total of 4288 incidents was found and due to the large number a random, weighted sample of 200 incidents was reviewed. The sample was screened to identify those which are not "cases" and it was found that 119 incident reports did not meet the selection criteria. In these reports it was mentioned that the patient required oxygen therapy or had poor oxygenation levels but there was no problem identified involving the oxygen therapy itself (e.g. baby delivered by emergency caesarean section, required O2; found patient lying on the floor, oxygen sats and BP was low).

81 reports did meet the selection criteria and they were analyzed. From the free text description it was possible to identify some common themes and these are illustrated in the following table:

Themes		**Numbers**	**Total**
Administration of oxygen therapy	No oxygen administered Delay or wrong dose/gas Communications problems Saturations not monitored	11 10 7 7	**35**
Equipment	Lack of equipment Empty oxygen cylinder User error Faulty equipment	14 14 3 2	**33**
Other			**13**
Total			**81**

From the sample reviewed, 35 incident reports relate to the **administration of oxygen therapy**.

- In 11 reports the patient did not receive oxygen although it was prescribed. Most of the cases occurred during a transfer, for example

  'Patient on full ventilation was transferred from bed space one to bed space three with no oxygen'.

  'The patient had not received oxygen therapy during transfer despite her PO2 being 5.45 in A&E'.

  'Patient transferred from A+E to the unit with BIPAP mask on and tubing connected to BIPAP machine. Patient looked to be struggling to breathe and catch breath… The machine was found to be off, patient transferred without battery pack from AE'.

- In four reports it was described that a wrong dose has been administered, for example the patient was prescribed 2l/min and received 8l/min; patient was connected to oxygen cylinder but the flow rate was set to zero

- In four reports it was described that the wrong gas has been administered; in all cases air had been given instead of oxygen

- In two reports it was described that there was a delay of the administration of oxygen; the delay was due to

  'Wall oxygen was not functional, and when the O2 cylinder was fetched there was a delay in opening the valve'

  '*Patient without oxygen cylinder for extended period due to delay in porters changing cylinder'*

- Seven reports describe communication problems; these are mainly related to staff not being informed that the patient requires oxygen. Examples are

  'Patient arrived to the ward on oxygen. In the nurse handover to the ward it was not stated that patient required oxygen'.

  '*As patient on continuous oxygen, transport home should have been ordered to accommodate continuous oxygen. Ambulance arrived and would not accept patient as she required continuous oxygen'*.

- In seven incident reports it was described that saturation levels were not recorded or monitored. Examples are:

  'Observations recorded - SPO2 84% on air - No sats recorded during post procedure recovery although the Staff Nurse had given intermittent oxygen therapy'.

  'Patient had no saturation monitor attached. Saturations found to be 47 when monitor attached'.

From the sample reviewed, 33 reports relate to oxygen **equipment**.

- 14 reports describe a lack of equipment and the items missing on the ward were saturation monitors, oxygen cylinder, oxygen ports, flow meter and CPAP equipment.
- 14 reports describe that the oxygen cylinder was found empty; examples from the free text description are:

  'Patient needed transfer - portable oxygen cylinder on ward empty'

  'Patient had been left with portable oxygen on and this had run out'
- Three reports relate to a user error; it was described that the suction was connected to the oxygen outlet; the water circuit had been set up incorrectly, the BIPAP machine was not set up correctly and the nasal BIPAP mask was applied upside down
- Two reports describe faulty equipment and these incidents relate to the oxygen tubing and the wall outlet.

13 **other** incidents were reported and these relate to a variety of issues.

- 5 incident reports describe a collision with oxygen equipment; these are:

  - Flow meter fell of the wall into the cot and hit the patient's head

  - Cylinder rolled off the bed and hit the patient's leg

  - Patient fell to floor and hit his head on oxygen cylinder next to bed

  - Oxygen cylinder placed in bathroom with patient, patient accidentally knocked over the cylinder which fell onto his foot

  - Patient tripped over an oxygen line
- Two reports describe the risk of smoking and receiving oxygen therapy at the same time; patients tried to light a cigarette while on oxygen and suffered burns to face, hands and chest
- Two reports relate to the audible alarm of ventilators; the reports describe that the sound was turned off/ on level one so that staff could not hear the alarm and were not immediately notified that there was a problem
- One report describe the risk of receiving morphine and oxygen therapy; a patient had been given 10mg morphine iv and was administered oxygen (dose unknown), the patient developed type 2 respiratory failure
- One incident occurred where the crash buzzer wasn't clearly audible due to the noise of the oxygen system
- One report described that the oxygen humidification system was set up to high and the water chamber and tubing coming from water chamber were untouchable hot (system was set for 35', the chamber temperature was 55')
- One incident was reported in which a patient pulled the O2 sats probe apart

Specialty and degree of harm

The following table shows the degree of harm by specialty.

	Degree of Harm					
Specialty	Death	Low	Moderate	No Harm	Severe	Total
Accident and Emergency		1				1
Anaesthetics				3		3
Diagnostic services			2	2		4
Medical specialties	1	8	5	25	1	40
Not applicable				1		1
Obstetrics and gynaecology		2		6		8
Other		3	2	1		6
Other specialties			1	2		3
Surgical specialties		4	2	9		15
Unknown		1		1		2
Total	1	19	12	50	1	83

The table shows that the majority of incidents reviewed occurred within the medical specialty.

The table also shows that the majority of incidents did result in no harm or low harm to the patient. One incident was reported, where the degree of harm was severe; however, from the free text description the incident does not seem to have resulted in permanent harm.

> *Patient was taken for a home assessment by OT/PT. Ambulance with O2 was organised for 12.00 for return. A full O2 cylinder was taken for visit. Ambulance didn't arrive till 13.30 ... We phoned that we were running out of O2 ... , phoned again at that O2 was now empty. However, ambulance arrived 20 minutes later. Patient was not in respiratory distress this time. O2 given by ambulance crew*.

One incident was reported where the degree of harm was death; in this reports it was described that a patient was being transferred with 100% high flow oxygen in situ. On arrival to the ward the oxygen ran out and immediate action was taken to connect the patient to the main oxygen supply. The patient was transferred to her bed and had a respiratory arrest followed by cardiac arrest; resuscitation began immediately but was unsuccessful and the patient died.

4. Conclusions

The NRLS database has been searched for incidents, which relate to oxygen therapy in acute/general hospitals. A total of 4288 incidents were found and due to the large number a random, weighted sample of 200 incidents was reviewed. It was found that 83 incidents from the sample met the selection criteria.

From the free text description it was possible to identify a range of risk factors for patients requiring oxygen therapy. These are related to the administration of oxygen and range from not receiving oxygen although required, to receiving the wrong dose or the wrong gas. It was also found that problems occur when saturation levels are not monitored or patient's oxygen requirements are not communicated among staff.

Further incidents were reported, which related to the oxygen equipment. It was found that there is a shortage of equipment on some wards and that in several cases the oxygen cylinder was found empty. Incidents also occurred because the equipment was faulty or was not used correctly.

A variety of other issues were reported relating to oxygen therapy and these are injuries due to unrestrained equipment, burns because of smoking, respiratory depression due to morphine and oxygen and harm due to hot water from the oxygen humidification system.

Although only 40% of the sample reviewed did meet the selection criteria, it was possible to identify some common themes and risk factors for patient receiving oxygen therapy and to get a better understanding of what types of incidents are reported to the NRLS relating to oxygen therapy in acute/general hospitals.

D.2 Using the Oxygen Incident Categorization Program

The Reading Form

The layout of the reading form is in two parts:

On the top, left side are the record navigation buttons and the drop-down choice boxes for the Case status and the Context. Below this are the collection of fields from the incident reports and the reader's notes field is at the bottom.

On the right are the categorization tree and the readers help buttons for the category headings.

Definitions

An accessory:

An accessory is anything beyond the flow meter that is used for passive oxygen therapy. E.g. Humidifier, tubing, nebuliser, mask, nasal cannula (specs), headboxes, tracheostomy connections.

Other Equipment:

Equipment attached to an oxygen supply instead of a flow meter, or anything used for assisted breathing. E.g. Ventilators, CPAP, NIPPV or bag-and-valve are 'Other Equipment'. Heated humidifiers and oxygen concentration monitors used with headboxes are also 'Other Equipment'.

A case:

Any incident where oxygen therapy was not administered when it should have, failed during therapy or was in some way implicated in the incident. External factors such as other therapies or medications that cause the patient's condition to change and thus affect the therapy should be included. Instances where oxygen therapy was correctly administered as a result of some other incident should not be included.

Context:

The context is the situation or place of the incident. They deal mainly with "place", but there are some "situation" contexts too. Some assumptions may need to be made here. If the event moved to another area, select the area it started in. Situation takes precedence over place. E.g. If it was a Crash Call, choose 'Internal Emergency' regardless of where the patient was. You may have to make your best guess with this, but don't be shy to select "don't know".

The list should be self explanatory, but if in doubt call or email Marcus.

Rules

The following rules must be applied when considering any record.

1. Always assume the worst case when details are not specified.
2. Even if there appears to have been no harm, each report must be considered an incident.

3. Hyperbaric oxygen therapy is excluded.
4. Incidents in operating theatres are to be excluded. If this is not stated in the report, assume the incident took place in a ward setting. Theatre recovery, ITU, HDU and Critical care are however to be included.
5. Home oxygen therapy is to be excluded.
6. Clinical Error can be either stated or inferred. If it is obvious to you that there was a clinical error then make this choice.

Categorizing Incident Records:

Please note that the following list is not exhaustive and that there may be cases where the cause is unspecified in the category tree but still fits into a category group. For example; there may be equipment failures where the equipment is not listed here, like CPAP or NIPPV devices.

It is permissible to choose more than one category. Many incidents are a result of multiple causes or are cascaded failures, where one failure leads to another.

If there is any doubt, choose the “For Discussion” check box. You can still categorize the incident as you think fit as well as ticking this box. Please remember to add a comment in reader’s notes to indicate why you want to discuss this incident.

Help is available by clicking the “?” button next to each category heading in the tree.

1. Equipment:

Any incident where the problem was caused or exacerbated by some problem with the equipment. This may include equipment not operating correctly, not operating at all, or use error.

a. Piped Supply:

These are cases where the piped supply has either stopped, produced a low output or is unavailable. Examples include; leaking, jammed or worn outlets that expel flow meters or other equipment or will not allow equipment to be connected. Wrong gas is also included here, and is linked to ‘Human error. Please note; ‘Not enough outlets’ is a lack of resources.

b. Cylinder Supply:

Empty cylinders, Jammed or leaking cylinder valves or regulators, Faulty pressure gauges, Regulators that will not go on or come off when cylinders are replaced, Wrong gas (linked with human error).

c. Flow meter:

Leaking or blocked flow meters, incorrect flow indication or physical damage.

d. Accessory Error:

Blocked humidifiers or tubing. Cut or crushed tubing. Poorly fitting connections or broken mask elastic straps. Use error is also included here.

e. Monitoring Equipment:

Faulty or incorrect use of patient monitoring equipment that could affect the therapy; like pulse oximeters or blood gas analysers.

f. Other Equipment:

Faults or incorrect use of any other equipment delivering or monitoring oxygen therapy. E.g. Ventilators, CPAP or NIPPV.

2. Human Error:

Any instance where people act incorrectly or fail to act correctly.

a. Communication Error:

Cases where people are not informed or are misinformed. Bad or missing patient's notes, Therapy not properly specified, nursing staff not keeping other staff informed.

b. Setup and Administration:

Wrongly assembled therapy, Humidifiers incorrectly used or not used when high flow rates are set, masks left on when the supply is turned off, badly positioned nasal cannulae or masks, wrong gas, wrongly cut bubble tubing, inadequately monitored therapy.

c. Clinical Error:

If the incident report states that there was a diagnostic, treatment or other clinical decision error, or if you are certain that there was an error of clinical judgement or decision.

d. Patient Monitoring:

Failure to monitor the patient. Failure to monitor the therapy (e.g. empty humidifiers or depleted cylinders) are setup and administration errors.

e. Other Human Error:

If a human error incident does not fit any of the above please describe it in the notes box.

External:

Any influence that is not under the direct control of the clinical staff. Management issues, security issues or environmental issues for example.

f. Lack of Resources (Things):

Cases where equipment or any required item is not available, not enough cylinders, wall ports, accessories or beds. Also consider incidents caused by faulty equipment left unattended to and so unavailable.

g. Ward Management:

Lack of staff, wrong grade or speciality of staff, poor knowledge causing delay or cascading to setup error, negligence or poor patient management.

h. Tampering:

Visitors or non clinical staff interfering with the therapy or causing a cascading incident by, for example, changing the setup of monitoring equipment.

i. Patient's Actions:

Misplacement of masks and cannulae, failure to co-operate, entanglement during sleep, disconnection from source due to movement. If the patient has tampered with the therapy, then choose intentional patient actions.

j. Institutional:

External factors that originate beyond the ward or department. Examples of communication issues are; porters not told about empty cylinders, or porters sent to the wrong place with a patient (especially if this leads to cylinder depletion). Procurement and stores problems are linked with lack of resources. Maintenance issues could be jammed doors or broken lifts. Environmental/infrastructure problems include lack of space, poor light, narrow doorways or excessive noise.

k. Other External:

If an external factor is not listed, please describe it in the notes box.

D.3 Combinations of Hazards – Selective Sorting

Table Appendix D.3-1 Selective sorting of records and elements.

	Harm	Count	IPP	CEPM	WMSK	CET	PMPC	PMPO	ISC	IMT	OHE	CCE	CPT	SAM	CPN	LRC	LRA	CE	AOP	SAA	LRB	LRWP	PACI	IEI	OEUF	IPS	OE	IMC	PAU	PMBG	AUE	SAF	MEF	OEF	PWG	CED	SAH	WMSS	WMSN	CFC	AF	CRP	FF	PS	CWG	TV
	Severe	11	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	TRUE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	10	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	9	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	9	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	9	FALSE	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	8	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	8	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	8	TRUE	TRUE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE
	Severe	7	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	FALSE	TRUE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	7	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	6	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	6	TRUE	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	6	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	6	FALSE	TRUE	TRUE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	6	TRUE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	TRUE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE

	Harm	Count	IPP	CEPM	WMSK	CET	PMPC	PMPO	ISC	IMT	OHE	CCE	CPT	SAM	CPN	LRC	LRA	CE	AOP	SAA	LRB	LRWP	PACI	IEI	OEUF	IPS	OE	IMC	PAU	PMBG	AUE	SAF	MEF	OEF	PWG	CED	SAH	WMSS	WMSN	CFC	AF	CRP	FF	PS	CWG	TV
	Severe	6	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	6	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	TRUE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	5	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	FALSE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE
	Severe	5	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	5	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	4	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	4	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	4	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	4	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	4	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	TRUE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	TRUE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE

	Harm	Count	IPP	CEPM	WMSK	CET	PMPC	PMPO	ISC	IMT	OHE	CCE	CPT	SAM	CPN	LRC	LRA	CE	AOP	SAA	LRB	LRWP	PACI	IEI	OEUF	IPS	OE	IMC	PAU	PMBG	AUE	SAF	MEF	OEF	PWG	CED	SAH	WMSS	WMSN	CFC	AF	CRP	FF	PS	CWG	TV
	Severe	4	TRUE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	4	FALSE	FALSE	FALSE	TRUE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	3	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	3	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	3	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	3	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	3	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	2	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	2	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	2	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE
	Death	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE

	Harm	Count	IPP	CEPM	WMSK	CET	PMPC	PMPO	ISC	IMT	OHE	CCE	CPT	SAM	CPN	LRC	LRA	CE	AOP	SAA	LRB	LRWP	PACI	IEI	OEUF	IPS	OE	IMC	PAU	PMBG	AUE	SAF	MEF	OEF	PWG	CED	SAH	WMSS	WMSN	CFC	AF	CRP	FF	PS	CWG	TV
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	2	FALSE	FALSE	FALSE	TRUE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	1	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	1	FALSE	FALSE	FALSE	TRUE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Death	0	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
	Severe	0	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE	FALSE
Severe	105	420	57	48	47	35	28	23	24	19	19	15	12	12	12	10	10	8	9	10	6	6	6	8	8	6	6	7	4	6	6	6	2	3	4	4	2	3	3	0	0	1	1	1	1	1
Death	30	118	2	3	0	6	1	3	2	0	0	3	2	2	0	1	1	2	1	0	3	2	2	0	0	1	1	0	2	0	0	0	2	1	0	0	1	0	0	1	1	0	0	0	0	0
Total	135	538	59	51	47	41	29	26	26	19	19	18	14	14	12	11	11	10	10	10	9	8	8	8	8	7	7	7	6	6	6	6	4	4	4	4	3	3	3	1	1	1	1	1	1	1

D.4 Hazard list comparison and Risk Analysis.

The following table lists in each column, the hazards identified during the observational research alongside the hazard themes from the questionnaire study and the taxonomy elements, with those relating to each other in each row. A red cell indicates that no corresponding hazard, hazard theme or taxonomy element could be identified for that row and an orange cell indicates partial similarity.

The risk scores from the questionnaire and the incident report studies are summed to produce the ‘Risk Sum’ value in the last column. This final value was carried to the aggregated hazard analysis in Appendix D.5, Table Appendix D.5-1

Table Appendix D.4-1 Hazard Identification comparison and Risk Analysis.

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
1	Incorrect clinical decision or action	Clinical Error	Clinical Error - Diagnosis Clinical Error - Treatment Clinical Error - Patient Management		0.007	0.00058 0.10602 0.06097	0.17491
2	Failure to recognize and act on an imminent therapy failure	Lack of Therapy Monitoring	Setup and Admin - Monitoring the therapy		0.024	0.00160	0.02535
3	Unauthorized or inappropriate action by others	Tampering	Tampering - Unauthorised staff		0.002	0.00009	0.00180
4	An environmental factor promotes inappropriate action		Institutional - Environment/Infrastructure			0.00577	0.00577
5	Non clinical staff rectifying an environmental fault		Institutional - Maintenance			0.00410	0.00410
6	Distraction caused by activity on the ward		Institutional - Environment/Infrastructure	Interruption/distraction during setting up		0.00577	0.00577
7	Latent error causes a failure in communication or process	Guidelines Communication	Institutional - Procedure/Protocol Institutional - Structure/Communication		0.024 0.014	0.10304 0.03237	0.17295
8	Patient management errors when patients arrive after transfer	Inadequate Patient Care Patient Transfer Problem	Clinical Error - Patient Management		0.012 0.017	0.06097	0.09037
9	Inadequacy of pro forma or another communication tool	Prescription Communication Patient's Notes	Communication - Prescription/Treatment order Institutional - Structure/Communication Communication - Patient Notes		0.058 0.014 0.003	0.02209 0.03237 0.01258	0.14186
10	Innocent action by visitor to aid patient comfort compromises this therapy	Patient Comfort			0.042		0.04187
12	Visitors tampering with therapies	Tampering	Tampering - Visitor		0.002	0.00033	0.00204
13	Clinical activity interfering with the therapy	Training Guidelines	Ward Management - Staff knowledge and skills Institutional - Procedure/Protocol		0.026 0.024	0.30900 0.10304	0.46153
14	Administering or adjusting another therapy causes interference with this one		Clinical Error - Treatment			0.10602	0.10602

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
15	Wrong type of accessory used for a particular therapy setup	Training Guidelines Setup Error Wrong Type Of Accessory	Ward Management - Staff knowledge and skills Setup and Admin - Assembly		0.026 0.024 0.042 0.006	0.30900 0.02213	0.42865
18	Process or patient management errors moving patients from one bed to another	Training Inadequate Patient Care Patient Transfer Problem	Clinical Error - Patient Management Institutional - Procedure/Protocol		0.026 0.012 0.017	0.06097 0.10304	0.21900
20	Calls for assistance unanswered	Training Inadequate Patient Care	Communication - Clinical Assistance/Examination		0.026 0.012	0.01974	0.05781
21	Patient requests or needs unfulfilled	Inadequate Patient Care	Communication - Clinical Assistance/Examination		0.012	0.01974	0.03221
22	Impaired speech due to the face mask or other aspect of the therapy making communication difficult	Communication			0.014		0.01365
23	Communication failures at patient hand-over	Training Guidelines Communication	Institutional - Procedure/Protocol	Communication problems at handover	0.026 0.024 0.014	0.10304	0.16618
24	Missing or incomplete patient notes	Training Communication Patient's Notes	Communication - Patient Notes		0.026 0.014 0.003	0.01258	0.05524
25	Incorrect information in patient notes	Training Communication Patient's Notes	Communication - Patient Notes		0.026 0.014 0.003	0.01258	0.05524
26	Poor communication between doctors and nursing staff	Training Communication	Communication - Prescription/Treatment order		0.026 0.014	0.02209	0.06134
27	Environmental factors such as noise masking calls for assistance	Patient Comfort	Institutional - Environment/Infrastructure	Noisy environment masked low saturation alarm	0.042	0.00577	0.07376

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Communication			0.014		
		Inadequate Patient Care			0.012		
28	Communication failures between clinician and patient during an examination	Training	Communication - Clinical Assistance/Examination		0.026	0.01974	0.05899
		Communication			0.014		
29	Nursing staff not responding to requests or orders from doctors	Prescription	Communication - Prescription/Treatment order		0.058	0.02209	0.20493
		Dosage Error			0.086		
		Training			0.026		
		Communication			0.014		
30	Prescriptions or treatment orders incorrect or not made	Prescription	Communication - Prescription/Treatment order		0.058	0.02209	0.24732
		Dosage Error			0.086		
		Training			0.026		
		Setup Error			0.042		
		Communication			0.014		
31	Spectacles or other obstructions on the face	Training			0.026		0.15869
		Guidelines			0.024		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Cylinder Fall			0.014		
		Accessory Fit Problem			0.011		
32	Position of cylinder at the bed side causes Physical obstruction	Training		Cylinder placement - dangerous position	0.026		0.06708
		Guidelines			0.024		
		Cylinder Fall			0.014		
		Cylinder Placement			0.002		
		Patient Access			0.002		
32.1	Position of cylinder at the bed side causes unknown cylinder contents	Empty Cylinder	Setup and Admin - Monitoring the therapy		0.099	0.00160	0.24087
		Training			0.026		
		Guidelines			0.024		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring Cylinder Placement			0.065 0.024 0.002		
32.2	Position of cylinders at the bed side causes patients movements to be restricted by tubing position	Training Guidelines Patient Comfort Setup Error Cylinder Fall Cylinder Placement	Setup and Admin - Assembly		0.026 0.024 0.042 0.042 0.014 0.002	0.02213	0.17176
33	Surplus equipment cluttering the ward area		Institutional - Environment/Infrastructure			0.00577	0.00577
34	Tubing pinched in furniture or other equipment at the bed side	Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring	Setup and Admin - Monitoring the therapy	Tubing occluded - Kinked/Knotted	0.065 0.024	0.00160	0.09085
35	Mistakes or equipment failures when changing from portable to installed monitoring or vice-versa	Training Guidelines	Monitoring Equipment - Fault Monitoring Equipment - Use Error		0.026 0.024	0.00255 0.00051	0.05255
36	Equipment improperly checked	Training Guidelines	Institutional - Procedure/Protocol		0.026 0.024	0.10304	0.15252
37	Physical failure of a patient connected accessory	Lack of Oxygen (Hypoxia) Patient Comfort Lack of Therapy Monitoring	Accessory - Faulty		0.065 0.042 0.024	0.00147	0.13259
38	Technical or physical failures of the bed or associated equipment	Patient Comfort	Other Equipment - Faulty		0.042	0.00753	0.04940
39	Interference from an environmental factor affecting a nurses actions in the use of equipment	Setup Error	Institutional - Environment/Infrastructure		0.042	0.00577	0.04816
40	Failure to respond to an equipment alarm or warning	Training Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring	Setup and Admin - Monitoring the therapy		0.026 0.065 0.024	0.00160	0.11644

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
41	Failure of staff to communicate regarding equipment required in patient transfer	Training Guidelines Communication Lack Of Equipment Patient Transfer Problem	Institutional - Procedure/Protocol		0.026 0.024 0.014 0.011 0.017	0.10304	0.19387
42	Environmental issues like noise or cramped space cause visitors actions to interfere with the therapy	Cylinder Fall	Institutional - Environment/Infrastructure		0.014	0.00577	0.01994
43	Human error by clinical staff when monitoring patients	Training Patient Condition Inadequate Patient Care Lack of Patient Monitoring	Patient Monitoring - Patient Condition		0.026 0.016 0.012 0.019	0.05019	0.12330
44	Undetected disconnection of patient monitoring equipment	Training Lack of Patient Monitoring	Monitoring Equipment - Use Error		0.026 0.019	0.00051	0.04475
45	Failure to respond to or implement patient monitoring	Training Guidelines Patient Condition Inadequate Patient Care Lack of Patient Monitoring	Patient Monitoring - Patient Condition		0.026 0.024 0.016 0.012 0.019	0.05019	0.14719
46	Failure to respond to patient or therapy monitoring alerts due to a lack of staff	Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring Patient Condition Inadequate Patient Care Lack of Patient Monitoring Lack Of Staff	Ward Management - Staff numbers		0.065 0.024 0.016 0.012 0.019 0.003	0.00385	0.14403
47	Patient actions adversely affecting patient monitoring	Patient Compliance Lack of Patient Monitoring	Patient Actions - Unintentional		0.079 0.019	0.00269	0.10060

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
48	Failure of patient or therapy monitoring to detect a therapy disconnection	Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring Lack of Patient Monitoring Accessory Not Connected Mask Related Suffocation	Setup and Admin - Monitoring the therapy		0.065 0.024 0.019 0.007 0.006	0.00160	0.12248
49	Failure to detect patient entanglement in oxygen tubing	Training Lack of Oxygen (Hypoxia) Patient Comfort Lack of Therapy Monitoring Inadequate Patient Care Lack of Patient Monitoring Entanglement - Tubing	Setup and Admin - Monitoring the therapy	Tubing entanglement	0.026 0.065 0.042 0.024 0.012 0.019 0.006	0.00160	0.19506
50	Failure to detect cylinder depletion when in use	Empty Cylinder Training Guidelines Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring	Cylinder - Empty		0.099 0.026 0.024 0.065 0.024	0.02749	0.26506
51	Environmental factor obscuring a clear view of the patient	Inadequate Patient Care Lack of Patient Monitoring	Institutional - Environment/Infrastructure		0.012 0.019	0.00577	0.03687
52	Environmental factor obstructing access to the patient	Patient Access	Institutional - Environment/Infrastructure		0.002	0.00577	0.00747
53	Accessory incorrectly administered or moved into an incorrect position by clinical staff	Training Guidelines Lack of Oxygen (Hypoxia) Patient Comfort Setup Error Accessory Fit Problem Mask Related Suffocation	Accessory - Out of Place		0.026 0.024 0.065 0.042 0.042 0.011 0.006	0.00526	0.22091

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
54	Failure to notice an incorrectly positioned accessory	Training	Accessory - Out of Place		0.026	0.00526	0.21513
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Lack of Therapy Monitoring			0.024		
		Accessory Fit Problem			0.011		
55	Changing a patients posture or position interferes with the therapy	Training			0.026		0.20095
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Posture/Positioning			0.002		
56	Preparing a patient for transfer interferes with the therapy	Training	Clinical Error - Patient Management		0.026	0.06097	0.23527
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Patient Transfer Problem			0.017		
57	Moving a patient between bed and chair causes interference with the therapy	Training	Clinical Error - Patient Management		0.026	0.06097	0.26585
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Mask Related Suffocation			0.006		
58	Incorrect action when responding to a change in a patients condition	COPD Management	Ward Management - Staff knowledge and skills		0.112	0.30900	0.65051
		Dosage Error			0.086		
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Patient Condition			0.016		
		Inadequate Patient Care			0.012		
59	Incorrect actions at patient handover	Training	Institutional - Procedure/Protocol		0.026	0.10304	0.23167
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Communication			0.014		
60	Incorrect actions during patient transfer	Training	Ward Management - Staff knowledge and skills		0.026	0.30900	0.45509
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Inadequate Patient Care			0.012		
		Patient Transfer Problem			0.017		
		Communication With Porters			0.002		
61	Failure to act on a detected therapy administration error	Dosage Error	Ward Management - Staff knowledge and skills		0.086	0.30900	0.54079
		Training			0.026		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Inadequate Patient Care			0.012		
62	Failure to detect that the therapy has terminated early	Empty Cylinder	Setup and Admin - Monitoring the therapy		0.099	0.00160	0.30111
		Dosage Error			0.086		
		Training			0.026		
		Lack of Oxygen (Hypoxia)			0.065		
		Lack of Therapy Monitoring			0.024		
63	Failure to act on a detected early therapy termination	Empty Cylinder	Ward Management - Staff knowledge and skills		0.099	0.30900	0.60457
		Dosage Error			0.086		
		Training			0.026		
		Lack of Oxygen (Hypoxia)			0.065		
		Inadequate Patient Care			0.012		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Cylinder Replacement/Refilling			0.007		
64	Equipment delivering another therapy fails causing interference with this one	Dosage Error Guidelines Lack of Oxygen (Hypoxia)	Other Equipment - Faulty		0.086 0.024 0.065	0.00753	0.18275
65	A required action related to another therapy causes a distraction which compromises this therapy	Lack of Oxygen (Hypoxia) Setup Error			0.065 0.042		0.10788
66	A patient takes action related to another therapy, which compromises this one	Patient Compliance Lack of Oxygen (Hypoxia) Setup Error	Patient Actions - Unintentional		0.079 0.065 0.042	0.00269	0.18985
67	Accessory moved into an incorrect position by Patient	Patient Compliance Lack of Oxygen (Hypoxia) Patient Comfort Setup Error Lack of Therapy Monitoring Accessory Fit Problem	Accessory - Out of Place		0.079 0.065 0.042 0.042 0.024 0.011	0.00526	0.26881
68	Unintentional action by patient interferes with the therapy	Lack of Oxygen (Hypoxia) Setup Error Lack of Therapy Monitoring	Patient Actions - Unintentional	Confused/agitated movements by patient	0.065 0.042 0.024	0.00269	0.13433
69	Unauthorized or inappropriate action by the patient	Patient Compliance Lack of Oxygen (Hypoxia) Setup Error Tampering	Patient Actions - Compliance/Intentional		0.079 0.065 0.042 0.002	0.01515	0.20402
70	Action taken by a patient related to natural relief compromises the therapy	Lack of Oxygen (Hypoxia) Patient Comfort Lack of Therapy Monitoring	Setup and Admin - Monitoring the therapy		0.065 0.042 0.024	0.00160	0.13271
71	Action taken by a patient to relieve discomfort compromises the	Lack of Oxygen (Hypoxia)	Setup and Admin - Monitoring the therapy		0.065	0.00160	0.17511

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
	therapy	Patient Comfort Setup Error Lack of Therapy Monitoring			0.042 0.042 0.024		
72	Patient refuses to co-operate with clinical staff regarding the therapy	Patient Compliance Lack of Oxygen (Hypoxia)	Patient Actions - Compliance/Intentional		0.079 0.065	0.01515	0.15992
73	Patient has to take action to enable them to talk, eat or drink	Lack of Oxygen (Hypoxia) Setup Error Lack of Therapy Monitoring	Patient Actions - Unintentional		0.065 0.042 0.024	0.00269	0.13433
73.1	Patient has to take action to enable them to take oral meds	Lack of Oxygen (Hypoxia) Setup Error Lack of Therapy Monitoring	Patient Actions - Unintentional		0.065 0.042 0.024	0.00269	0.13433
74	Actions by patient causes them to become entangled in the oxygen tubing	Lack of Oxygen (Hypoxia) Patient Comfort Setup Error Lack of Therapy Monitoring Entanglement - Tubing Deliberate Self Harm - Tubing	Patient Actions - Unintentional	Tubing entanglement	0.065 0.042 0.042 0.024 0.006 0.006	0.00269	0.18748
75	Actions by the patient interfere with the patient monitoring	Patient Compliance Lack of Patient Monitoring	Patient Actions - Unintentional		0.079 0.019	0.00269	0.10060
77	Movements or actions during sleep compromise the therapy	Lack of Oxygen (Hypoxia) Patient Compliance Lack of Therapy Monitoring	Patient Actions - Unintentional		0.065 0.079 0.024	0.00269	0.17121
80	Innocent action by patient compromises the therapy	Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring Patient Compliance	Patient Actions - Unintentional		0.065 0.024 0.079	0.00269	0.17121
82	Patient refuses to co-operate with the therapy by removing and ignoring requests to replace the accessory	Patient Compliance Lack of Oxygen (Hypoxia)	Patient Actions - Compliance/Intentional		0.079 0.065	0.01515	0.15992

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
90	The accessory has to be changed to relieve patient discomfort	Training Patient Comfort Setup Error Accessory Fit Problem			0.026 0.042 0.042 0.011		0.12062
91	The patients condition minimises communication and involvement	Communication Patient Condition			0.014 0.016		0.03006
92	Undetected change in patient condition	COPD Management Dosage Error Training Lack of Oxygen (Hypoxia) Patient Condition Inadequate Patient Care Lack of Patient Monitoring	Patient Monitoring - Patient Condition		0.112 0.086 0.026 0.065 0.016 0.012 0.019	0.05019	0.38645
93	Patient vomiting while an accessory is in position	Training Guidelines Lack of Oxygen (Hypoxia) Patient Condition			0.026 0.024 0.065 0.016		0.13139
96	A factor relating to design within the therapy or the environment causes staff to be distracted	Training Lack of Oxygen (Hypoxia)		Interruption/distraction during setting up	0.026 0.065		0.09109
97	A latent error in a defined procedure causes mistakes	Dosage Error Training Guidelines Lack of Oxygen (Hypoxia)	Institutional - Procedure/Protocol		0.086 0.026 0.024 0.065	0.10304	0.30385
98	Humidifier incorrectly set up, used inappropriately or not used when it should	Training Guidelines Lack of Oxygen (Hypoxia) Patient Comfort	Setup and Admin - Humidification		0.026 0.024 0.065 0.042	0.00080	0.21081

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Setup Error			0.042		
		Humidifier Set Up			0.011		
99	A lack of available equipment for therapy administration or monitoring	Lack of Oxygen (Hypoxia)	Lack of resources - Accessories		0.065	0.01765	0.16517
		Setup Error			0.042		
		Lack of Therapy Monitoring			0.024		
		Lack Of Equipment			0.011		
		Lack Of Cylinders			0.005		
100	Insufficient staff numbers to effectively manage patients receiving therapy	Lack of Oxygen (Hypoxia)	Ward Management - Staff numbers		0.065	0.00385	0.12421
		Lack of Therapy Monitoring			0.024		
		Inadequate Patient Care			0.012		
		Lack of Patient Monitoring			0.019		
101	Failure to correct a displaced accessory	Training	Accessory - Out of Place		0.026	0.00526	0.20385
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Inadequate Patient Care			0.012		
		Accessory Fit Problem			0.011		
105	A factor relating to design within the therapy or the environment causes setup error	Lack of Oxygen (Hypoxia)	Setup and Admin - Assembly		0.065	0.02213	0.13001
		Setup Error			0.042		
107	Mistakes in setting up the therapy	Dosage Error	Setup and Admin - Assembly		0.086	0.02213	0.27662
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Mask Related Suffocation			0.006		
		Flow Meter Not Turned On			0.006		
108	Undetected failed oxygen supply	Empty Cylinder	Pipeline - Supply Fail		0.099	0.00018	0.23367
		Training			0.026		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Lack of Oxygen (Hypoxia)			0.065		
		Lack of Therapy Monitoring			0.024		
		Inadequate Patient Care			0.012		
		Wall Supply Fault			0.002		
		Mask Related Suffocation			0.006		
109	Incorrect action taken when attempting to rectify a setup error	Dosage Error	Ward Management - Staff knowledge and skills		0.086	0.30900	0.53961
		Training			0.026		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Mask Related Suffocation			0.006		
		Flow Meter Not Turned On			0.006		
110	Therapy tubing disconnected in error	Training	Ward Management - Staff knowledge and skills	Tubing disconnect	0.026	0.30900	0.45548
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Accessory Not Connected			0.007		
		Mask Related Suffocation			0.006		
113	A change of accessory is incorrectly implemented	Training	Ward Management - Staff knowledge and skills		0.026	0.30900	0.45377
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Wrong Type Of Accessory			0.006		
		Mask Related Suffocation			0.006		
115	An accessory is displaced when a patient's position or posture is changed	Training	Accessory - Out of Place		0.026	0.00526	0.21684
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Lack of Therapy Monitoring			0.024		
		Accessory Fit Problem			0.011		
		Posture/Positioning			0.002		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
116	An accessory is incorrectly or inappropriately disconnected by clinical staff	Training Guidelines Lack of Oxygen (Hypoxia) Setup Error Inadequate Patient Care Accessory Not Connected Mask Related Suffocation	Ward Management - Staff knowledge and skills		0.026 0.024 0.065 0.042 0.012 0.007 0.006	0.30900	0.49184
117	An incorrect adjustment is made to the therapy	Dosage Error Training Guidelines Lack of Oxygen (Hypoxia)	Setup and Admin - Flowrate		0.086 0.026 0.024 0.065	0.00729	0.20810
118	Bubble tubing incorrectly cut	Training Setup Error	Setup and Admin - Assembly		0.026 0.042	0.02213	0.09012
119	Change either way between piped supply and cylinder incorrectly implemented	Training Lack of Oxygen (Hypoxia) Setup Error Mask Related Suffocation	Setup and Admin - Assembly		0.026 0.065 0.042 0.006	0.02213	0.16125
120	Failure by clinical staff to notice a patient disconnection	Training Lack of Oxygen (Hypoxia) Lack of Therapy Monitoring Inadequate Patient Care Accessory Not Connected	Setup and Admin - Monitoring the therapy		0.026 0.065 0.024 0.012 0.007	0.00160	0.13626
121	Failure to detect a setup error	Dosage Error Training Lack of Oxygen (Hypoxia) Setup Error Lack of Therapy Monitoring	Setup and Admin - Monitoring the therapy		0.086 0.026 0.065 0.042 0.024	0.00160	0.25031

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Flow Meter Not Turned On			0.006		
122	Flow rate incorrectly or inappropriately adjusted	COPD Management	Setup and Admin - Flowrate		0.112	0.00729	0.37360
		Dosage Error			0.086		
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Mask Related Suffocation			0.006		
		Flow Meter Not Turned On			0.006		
123	Therapy incorrectly or inappropriately set up when re-administered after a previous termination	Dosage Error	Setup and Admin - Assembly		0.086	0.02213	0.26533
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
125	Undetected humidifier water depletion	Training	Setup and Admin - Monitoring the therapy		0.026	0.00160	0.14598
		Patient Comfort			0.042		
		Setup Error			0.042		
		Lack of Therapy Monitoring			0.024		
		Humidifier Set Up			0.011		
126	Wrong type of accessory used for a particular therapy setup	Training	Setup and Admin - Assembly		0.026	0.02213	0.17228
		Guidelines			0.024		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Accessory Fit Problem			0.011		
		Wrong Type Of Accessory			0.006		
127	Failure to adequately monitor a patient during treatment with another therapy	Training	Patient Monitoring - Patient Condition		0.026	0.05019	0.21268
		Guidelines			0.024		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Condition			0.016		
		Inadequate Patient Care			0.012		
		Lack of Patient Monitoring			0.019		
128	Patient requirement incorrectly assessed	COPD Management	Clinical Error - Diagnosis		0.112	0.00058	0.37884
		Dosage Error			0.086		
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Patient Condition			0.016		
		Clinical Error			0.007		
129	Failure to respond to or implement therapy monitoring	Empty Cylinder	Setup and Admin - Monitoring the therapy		0.099	0.00160	0.28156
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Lack of Therapy Monitoring			0.024		
131	Incorrect action when responding to or implementing patient monitoring	Dosage Error	Patient Monitoring - Patient Condition		0.086	0.05019	0.25822
		Training			0.026		
		Lack of Oxygen (Hypoxia)			0.065		
		Inadequate Patient Care			0.012		
		Lack of Patient Monitoring			0.019		
134	Other medication interfering with this therapy	Prescription	Clinical Error - Treatment		0.058	0.10602	0.38441
		Dosage Error			0.086		
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
		Inadequate Patient Care			0.012		
		Clinical Error			0.007		
136	Therapy not set up according to prescription or treatment order	Prescription	Communication - Prescription/Treatment order	Communication - Prescribed therapy not administered	0.058	0.02209	0.34406
		Dosage Error			0.086		
		Training			0.026		
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Communication			0.014		
		Clinical Error			0.007		
137	A human factors issue with any equipment causes a functional failure because Equipment is applied differently to its intended use	Training	Other Equipment - Use Error		0.026	0.00904	0.20933
		Lack of Oxygen (Hypoxia)			0.065		
		Patient Comfort			0.042		
		Setup Error			0.042		
		Cylinder Fall			0.014		
		Accessory Fit Problem			0.011		
139	Bed spaces are in close proximity	Training	Institutional - Environment/Infrastructure		0.026	0.00577	0.12075
		Guidelines			0.024		
		Lack of Oxygen (Hypoxia)			0.065		
140	Two or more patients sharing a wall port or cylinder	Training	Lack of Resources - Cylinders		0.026	0.02896	0.21574
		Guidelines	Lack of resources - Wall ports		0.024	0.00670	
		Lack of Oxygen (Hypoxia)			0.065		
		Setup Error			0.042		
		Lack Of Equipment			0.011		
		Lack Of Wall Ports			0.007		
		Lack Of Cylinders			0.005		

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
141	Sensitive alarms and persistent nurse calls from patients	Inadequate Patient Care Lack of Patient Monitoring			0.012 0.019		0.03111
143	Staff are allowed to undertake tasks without adequate or relevant skills or knowledge	Training Guidelines Inadequate Patient Care	Ward Management - Staff knowledge and skills		0.026 0.024 0.012	0.30900	0.37096
145	No provision for the safe and organized storage of oxygen cylinders	Empty Cylinder Training Guidelines Lack of Oxygen (Hypoxia) Cylinder Fall	Institutional - Management		0.099 0.026 0.024 0.065 0.014	0.00030	0.22829
146	Lifts are shared with all building users		Institutional - Environment/Infrastructure	Infrastructure - Lifts unavailable		0.00577	0.00577
147	Not enough oxygen outlets for the number of patients requiring therapy	Guidelines Lack of Oxygen (Hypoxia) Inadequate Patient Care Lack Of Wall Ports	Lack of resources - Wall ports		0.024 0.065 0.012 0.007	0.00670	0.11538
148		Inadequate Patient Care COPD Management	Clinical Error - Patient Management	Nursing staff afraid of treating patient with oxygen because of COPD	0.012 0.112	0.06097	0.18526
149		Guidelines	Institutional - Procedure/Protocol		0.024	0.10304	0.12693
150		Cylinder Fall	Cylinder - Falling Cylinder		0.014	0.00177	0.01595
151		Manual Handling - Cylinders		Awkward handling of cylinders during transfer	0.007		0.00683
152		Wrong Gas	Pipeline - Wrong Gas		0.017	0.00237	0.01930
152.1		Wrong gas	Cylinder - Wrong Gas		0.017	0.00067	0.01760
153		Smoking		Smoking while on oxygen	0.013		0.01299
154		Delayed Action			0.007		0.00735

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
155		Patient Transfer Problem Communication		Communication problems with porters when arranging for patient transfer	0.017 0.014		0.03058
156		Excessive Work Load	Ward Management - Staff numbers		0.003	0.00385	0.00727
157		Flow Meter Fault	Flow meter - Faulty		0.003	0.00026	0.00367
158		Retrolental Fibroplasia			0.011		0.01129
159		CPAP/BIPAP Problems			0.007		0.00735
160		Tracheostomy		Tracheostomy dislodged	0.011		0.01129
161		Cylinder Identification			0.002		0.00171
162		Actions of Patient's Parents			0.006		0.00564
163		Regulator Faulty	Cylinder - Regulator/Pressure Gauge		0.002	0.00104	0.00275
164				Bedspaces not prepared			
165				Clinical Error - Making decisions without reference to diagnostic results			
166				Collision between patient and pipeline outlet hardware			
167				Communication/Structure - refusal to assess patient			
168				Contaminated pipeline			
169				Contamination hazard - Used accessories not disposed of and replaced			
170				Cylinder damage - Incorect positioning on trolley			
171				Cylinder Faulty - Cannot turn on gas			
172				cylinder faulty - leaking			
173				Cylinder management - Unsecured/Unrestrained			

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
174				Cylinder management error - Not turned off after use			
175				Cylinder Quality - New cylinder empty			
176				Deviations from accepted procedure			
177				Distraction of staff - Issue with this therapy puts other patients at risk			
178				Endo-Tracheal tube blocked			
179				Equipment design issue			
180				Equipment missing - Cylinder			
181				Equipment missing - Cylinder key			
182				Equipment missing - Flowmeter			
183				Equipment missing - Regulator			
184				Equipment not checked			
185				Faulty humidifier			
186				Faulty Schrader valve on cylinder jamming and preventing change of supply			
187				Fire hazard - Faulty nearby electrical equipment			
188				Flowmeter not properly attached to wall port			
189				Humidifier use error - Refilled with saline			
190				Inappropriate advice from unauthorized person			

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
191				Infection risk - Fungus in oxygen tubing (Can be caused by using non-sterile water in humidifier)			
192				Infrastructure - Emergency buzzer inaccessible			
193				Insufficient cylinder contents for transfer			
194				Interference from nursing tasks - Accidental therapy disconnection			
195				Lack of resources; sterile water for humidifiers			
196				Monitoring equipment - Physical harm from sensors			
197				Non-Standard equipment fitting sizes			
198				Oil used on oxygen outlet			
199				Other therapies - Unauthorized medications			
200				Oxygen flow impeded - Accessory blocked			
201				Oxygen Regulator Fire			
202				Patient left unattended			
203				Patient monitoring - Equipment unavailable			
204				Pressure/Abrasion sores from accessories			
205				Procedural error - Deligating clinical/nursing tasks to parents			

Hazard ID	Observed Hazard Types	Questionnaire Themes	Reported Incident Categories	Hazard Themes not in the Taxonomy	Quest Risk	Inc Risk	Risk sum
206				Procedureal delay - Cylinder restocking			
207				Procedureal delay - Examination			
208				Self Harm - Strangulation with oxygen tubing			
209				Setup - Oxygen not turned on			
210				Setup error - Venturi mask			
211				Staff knowledge/Skill - not able to identify an oxygen failure alarm			
212				staff unavailable - too busy			
213				Transfering without adequate escort			
214				Transport without oxygen			
215				Tubing damaged - Melted due to contact with hot surface			
216				Unauthorized administration of oxygen			
217				Unsuitable running repairs			
218				Use Error - Cylinder not switched on			
219				Ward management - Empty and full cylinders stored together			
220				Wrong wall port - Suction instead of oxygen			

D.5 Aggregated Hazard Analysis

Table Appendix D.5-1 Hazard analysis combining all results.

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
All	All	38	Technical or physical failures of the bed or associated equipment	Malfunctioning bed or associated equipment	Equipment failure	Disturbance of therapy, distracted staff	0.0494
All	All	5	Non clinical staff rectifying an environmental fault	Unexpected events due to non clinical maintenance work	Environmental control mechanism failure, Lack of vigilance	Unexpected and unpredictable influence on therapy	0.0041
All	External - Environment	185	Fire hazard - Faulty nearby electrical equipment	Fire in an oxygen enriched environment	Faulty electrical equipment at or near an oxygen enriched bedspace	Fire to bed linen, equipment or oxygen delivery accessories	
All	External - Infrastructure	146	Lifts are shared with all building users	Extended and unpredictable transfer times	No dedicated lift Access for patient transfers	Prolonged patient transfers leading to an increased possibility of cylinder depletion, increased possibility of lifts failing and of physical harm to other lift users	0.0058
All	External - Manufacturer	195	Non-Standard equipment fitting sizes	Non-Standard equipment fitting sizes	Manufacturing error, inappropriate modification	Setup cannot be completed	
All	External - Person	162	Actions of Paediatric Patient's Parents	Inapropriate actions by parents of paediatric patients	Poor communication and involvment with parents	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	0.0056
Clinical	External - Environment	52	Environmental factor obstructing access to the patient	Obstructed access to patient	Environmental factor	Delays, Reduced task capabilities, Physical harm	0.0075
Clinical	External - Environment	33	Surplus equipment cluttering the ward area	Obstructed access or confusion	Cluttered ward area	Ineffective equipment management, Physical obstructions, Reduced access, Confusion between used and full cylinders	0.0058
Clinical	External - Environment	39	Interference from an environmental factor affecting a nurses actions in the use of equipment	Equipment use error	Interference from an environmental factor	Therapy set up or monitoring errors	0.0482
Clinical	External - Environment	51	Environmental factor obscuring a clear view of the patient	Obscured view of patient	Environmental factor	Reduced patient monitoring, Impaired vigilance	0.0369
Clinical	External - Environment	27	Environmental factors such as noise masking calls for assistance	Unanswered calls for assistance	High levels of ambient noise	Impaired vigilance, No response to alarms from monitoring equipment and nurse calls	0.0738

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	External - Environment	96	A factor relating to design within the therapy or the environment causes staff to be distracted	Distracted or inattentive staff	Human factors: Difficulty in administering therapy	Incorrect or inadequate therapy, discomfort, physical harm	0.0911
Clinical	External - Infrastructure	190	Infrastructure - Emergency buzzer inaccessible	Emergency buzzer is out of reach or faulty	Poor room layout, equipment fault	Staff cannot call for assistance in an emergency in a side room	
Clinical	External - Institutional	149	Lack of or poorly constructed guidelines	Poor guidelines	Assessing requirement or applying therapy	Incorrect treatment	0.1269
Clinical	External - Institutional	97	A latent error in a defined procedure causes mistakes	Latent error in a procedure	Incorrectly defined procedure	Incorrect or inadequate therapy, discomfort, physical harm	0.3039
Clinical	External - Institutional	156	Excessive Work Load for Staff	Lack of staff or busy environment	Task overload, ward management failure, organizational failure	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	0.0073
Clinical	External - Other Therapy	159	CPAP/BIPAP Problems	Incorrect oxygen concentration during CPAP or BIPAP	Setup error, oxygen supply failure, equipment failure/use error	Hypoxia, distress, discomfort	0.0073
Clinical	External - Other Therapy	197	Other therapies - Unauthorized medications	Unauthorised medications	Patient administered or unprescribed medication	Therapy interference	
Clinical	External - Person	214	Unauthorized administration of oxygen	Oxygen administered by unauthorized person or without clinical authorization	Human error, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	Inappropriate therapy	
Clinical	Patient	64	Equipment delivering another therapy fails causing interference with this one	Interference with the therapy	Equipment Failure for another therapy	Incorrect or inadequate therapy, discomfort, physical harm	0.1827
Clinical	Patient	68	Unintentional action by patient interferes with the therapy	Undetected therapy failure	Patients actions	Incorrect or inadequate therapy, discomfort, physical harm	0.1343
Clinical	Patient	70	Action taken by a patient related to natural relief compromises the therapy	Suspension of therapy	Patient leaves the bed to go to the toilet	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff	0.1327
Clinical	Patient	71	Action taken by a patient to relieve discomfort compromises the therapy	Suspension of therapy	Patient changes position or moves between bed and chair	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff	0.1751

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Patient	73	Patient has to take action to enable them to talk, eat or drink	Suspension of therapy or food/drink not consumed	Patient has to suspend the therapy to enable them to talk, eat or drink	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, Food / drink not consumed, distracted staff	0.1343
Clinical	Patient	73.1	Patient has to take action to enable them to take oral meds	Suspension of therapy or oral meds not taken	Patient has to suspend the therapy to enable them to take oral meds	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, Oral meds not taken, distracted staff	0.1343
Clinical	Patient	74	Actions by patient causes them to become entangled in the oxygen tubing	Patient entanglement	Patient movements	Incorrect or inadequate therapy, discomfort, physical harm	0.1875
Clinical	Patient	77	Movements or actions during sleep compromise the therapy	Undetected therapy failure	Unintentional patient actions or movements	Interrupted therapy resulting in no therapy if this remains undetected	0.1712
Clinical	Patient	80	Innocent action by patient compromises the therapy	Undetected therapy failure	Unintentional	Interrupted therapy resulting in no therapy if this remains undetected	0.1712
Clinical	Patient	91	The patients condition minimises communication and involvement	Limited information, patient involvement and feedback	Lack of communication	Patient cannot report changes in condition or requirement leading to the possibility for sub-optimal therapy	0.0301
Clinical	Patient	66	A patient takes action related to another therapy, which compromises this one	Undetected therapy failure	Patients actions related to another therapy	Incorrect or inadequate therapy, discomfort, physical harm	0.1898
Clinical	Patient	93	Patient vomiting while an accessory is in position	Vomiting into a face mask	Lack of vigilance, ineffective patient monitoring	If the patient is wearing a face mask, there is a strong possibility of choking. The mask has to be removed while the patient is vomiting, resulting in reduced or no therapy.	0.1314
Clinical	Patient	153	Smoking	Fire	Smoking in an oxygen rich environment	Fire to bed linen or oxygen delivery accessories	0.0130
Clinical	Patient	82	Patient refuses to co-operate with the therapy by removing an accessory and ignoring requests to replace it	Misplaced accessory	Patient co-operation	Limited or no therapy and distracted staff	0.1599
Clinical	Patient	69	Unauthorized or inappropriate action by the patient	Undetected therapy failure	Unauthorized or inappropriate action by the patient	Incorrect or inadequate therapy, discomfort, physical harm	0.2040

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Patient	22	Impaired speech due to the face mask or other aspect of the therapy making communication difficult	Lack of communication through impaired speech	A face mask or other aspect of the therapy causing impairment	Limited communication	0.0137
Clinical	Patient Monitoring	92	Undetected change in patient condition	Undetected change in patient condition	Lack of vigilance, ineffective patient monitoring, interference from an environmental factor	Incorrect or inadequate therapy, discomfort, physical harm	0.3864
Clinical	Patient Monitoring	127	Failure to adequately monitor a patient during treatment with another therapy	Undetected change in patient condition	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm	0.2127
Clinical	Patient Monitoring	194	Monitoring equipment - Physical harm from sensors	Sensors left in the same position for too long	Human error, lack of knowledge/skill	Burns or pressure sores from sensor placements	
Clinical	Patient Monitoring	201	Patient monitoring - Equipment unavailable	No patient monitoring equipment available	Equipment management error, Patient management error	Patient cannot be monitored effectively, possibility of undetected condition changes	
Clinical	Patient Monitoring	44	Undetected disconnection of patient monitoring equipment	Undetected monitoring failure	Monitoring equipment disconnection	Patient monitoring error, Incorrect or inadequate therapy, discomfort, physical harm	0.0447
Clinical	Patient Monitoring	141	Sensitive alarms and persistent nurse calls from patients	Undetected therapy failure	Frequently occurring alarms	Desensitization to alarms resulting in Impaired vigilance, No response to alarms from monitoring equipment and nurse calls	0.0311
Clinical	Patient/External - Person	188	Inappropriate advice to patient from unauthorized person	Incorrect or inappropriate advice	Untrained staff, visitors giving advice	Inapropriate or incorrect action	
Clinical	Patient/Patient Monitoring	47	Patient actions adversely affecting patient monitoring	Interference with patient monitoring	Patients actions	Ineffective patient monitoring	0.1006
Clinical	Patient/Staff	72	Patient refuses to co-operate with clinical staff regarding the therapy	Suspension of therapy	Lack of patient co-operation	Increased possibility of therapy not being resumed, Reduced or interrupted therapy or no therapy if undetected, distracted staff	0.1599
Clinical	Patient/Therapeutic Subsystem	206	Self Harm - Strangulation with oxygen tubing	Self Harm - Strangulation with oxygen tubing	Patient not assessed as "At-risk", Lack of vigilance	Serious physical harm, Death, Traumatized staff and patients	
Clinical	Staff	175	Deviations from accepted procedure	Inappropriate deviation from accepted procedure	human error, lack of knowledge/skill, insufficient process checks	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Staff	14	Administering or adjusting another therapy causes interference with this one	Interference from adjustment of another therapy	Human error, lack of knowledge/skill, Lack of vigilance	Physical interference causing inadequate therapy	0.1060
Clinical	Staff	65	A required action related to another therapy causes a distraction which compromises this therapy	Staff distraction	Action required for the administration of another therapy	lack of vigilance, incomplete, Incorrect or inadequate therapy, discomfort, physical harm	0.1079
Clinical	Staff	9	Inadequacy of pro forma or another communication tool	Information missing or incorrect	An inadequate communication tool	Delays or incorrect decisions based on poor information	0.1419
Clinical	Staff	20	Calls for assistance unanswered	Unanswered calls for assistance	Lack of vigilance	Incorrect, Inadequate or No Therapy, discomfort, physical harm	0.0578
Clinical	Staff	100	Insufficient staff numbers to effectively manage patients receiving therapy	Lack of staff	Management error, Institutional issue	Sub-optimal patient care, Reduced patient monitoring, Impaired vigilance, Inconsistent patient care, Inappropriate action, inadequate or no therapy	0.1242
Clinical	Staff	109	Incorrect action taken when attempting to rectify a setup error	Incorrect action	Setup error and human error	Incorrect or inadequate therapy, discomfort, physical harm	0.5396
Clinical	Staff	18	Process or patient management errors moving patients from one bed to another	Patient placed in an inadequate bed space	Moving patients between bed spaces	Inadequate, incorrect or no therapy applied	0.2190
Clinical	Staff	128	Patient requirement incorrectly assessed	clinical error: diagnosis/assessment	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.3788
Clinical	Staff	13	Clinical activity interfering with the therapy	Unexpected influence on therapy by routine tasks.	Interference from clinical interventions to patient receiving oxygen therapy	Change induces ineffective therapy.	0.4615
Clinical	Staff	167	Communication/Structure - refusal to assess patient	Clinician cannot or will not assess patient	Institutional communication or structure errors	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff	7	Latent error causes a failure in communication or process	Latent error in communication or process methods	Human error - mistakes in process definitions	Following the defined process leads to error	0.1730
Clinical	Staff	164	Bed spaces not prepared	Bed spaces not adequately prepared for patients requiring therapy	Lack of staff, Task overload, ward management failure, organizational failure	Delayed or no therapy	
Clinical	Staff	6	Distraction caused by activity on the ward	Distraction of clinical staff	Unusual or intrusive activity on the ward	Impaired vigilance, Increased possibility of human error	0.0058

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Staff	4	An environmental factor promotes inappropriate action	Inappropriate or incorrect action - Staff	Human factors - An environment of excessive Noise, Light, Darkness or discomfort	Incorrect, Inadequate or No Therapy, discomfort, physical harm	0.0058
Clinical	Staff	143	Staff are allowed to undertake tasks without adequate or relevant skills or knowledge	No method available to prevent unauthorized staff attempting clinical or nursing tasks	Lack of skill/knowledge, protocol / procedure error	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	0.3710
Clinical	Staff	1	Incorrect clinical decision or action	Clinical Error - Undetected incorrect clinical decision or action	Incorrect information, lack of knowledge or skill, human error	Incorrect, Inadequate or No Therapy	0.1749
Clinical	Staff	8	Patient management errors when patients arrive after transfer	Patient placed in an incorrect ward or bed space.	Patient Management error	Inadequate, unreliable or no therapy	0.0904
Clinical	Staff	24	Missing or incomplete patient notes	Missing or incomplete patient notes	Human error - Notes mislayed or misfiled	Delays or incorrect decisions based on poor information	0.0552
Clinical	Staff	61	Failure to act on a detected therapy administration error	Failure to act on a Therapy administration error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.5408
Clinical	Staff	41	Failure of staff to communicate regarding equipment required in patient transfer	Unavailable equipment	Failure to communicate a requirement	Incorrect or inadequate therapy, discomfort, physical harm	0.1939
Clinical	Staff	30	Prescriptions or treatment orders incorrect or not made	Incorrect action	Communication, protocol or procedure failure	No therapy or incorrect therapy	0.2473
Clinical	Staff	29	Nursing staff not responding to requests or orders from doctors	Failure to act	Communication or protocol failure	No therapy or incorrect therapy	0.2049
Clinical	Staff	211	Transferring without adequate escort	Patients on oxygen therapy transferred without escort	Human error, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff	46	Failure to respond to patient or therapy monitoring alerts due to a lack of staff	No response to monitoring alerts	lack of staff	Incorrect or inadequate therapy, discomfort, physical harm	0.1440
Clinical	Staff	21	Patient requests or needs unfulfilled	Unfulfilled patient need	Failure to act	Incorrect, Inadequate or No Therapy, discomfort, physical harm	0.0322
Clinical	Staff	63	Failure to act on a detected early therapy termination	Failure to act on an early therapy termination	Human error	No therapy, discomfort, physical harm	0.6046
Clinical	Staff	23	Communication failures at patient hand-over	Poor communication at patient handover	Poorly defined process, not following procedure, complacency	Incorrect action or failure to act	0.1662

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Staff	26	Poor communication between doctors and nursing staff regarding setup or adjustment	Incorrect action or no action	Communication failure between clinical staff	No therapy or incorrect therapy	0.0613
Clinical	Staff	59	Incorrect actions at patient handover	Protocol/procedure error: Incorrect action	Handing over care from one team to another	Incorrect or inadequate therapy, discomfort, physical harm	0.2317
Clinical	Staff	25	Incorrect information in patient notes	Incorrect information entered into patient notes	Human error - Mistakes when writing notes, wrong patients notes written in	Incorrect action or failure to act	0.0552
Clinical	Staff/Cylinder	155	Delays or failures with Cylinder Replacement/Refilling	Lack of available cylinders	Request for replacement not made, request not received or handled by porters, insufficient central stock	Delayed or no therapy	0.0306
Clinical	Staff/Cylinder	161	Cylinder Identification	Staff unable to identify cylinder contents	Staff knowledge, improper/ unclear or missing content label/colour code	Wrong gas applied	0.0017
Clinical	Staff/Cylinder	216	Use Error - Cylinder not switched on	Cylinder not turned on at setup	Human error, lack of knowledge/skill, Communication error	No therapy	
Clinical	Staff/Cylinder	209	Staff knowledge/Skill - not able to identify an oxygen failure alarm	Staff unable to identify oxygen cylinders	Unmarked/labelled/coded cylinders, lack of knowledge/skill	Wrong gas, no therapy, delayed therapy	
Clinical	Staff/Cylinder	173	Cylinder management error - Not turned off after use	Cylinders placed in storage without being turned off	Human error	Depleted cylinders in storage, oxygen enriched storage area	
Clinical	Staff/External - institutional	210	staff unavailable - too busy	Staff unavailable	Lack of staff, Task overload, ward management failure, organizational failure	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff/External - Person	203	Procedural error - Delegating clinical/nursing tasks to parents	Clinical tasks inappropriately delegated to parents	lack of knowledge/skill, Human error, procedure/protocol error, lack of staff	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff/Patient	58	Incorrect action when responding to a change in a patients condition	Clinical error: incorrect action	Change in patients condition	Incorrect or inadequate therapy, discomfort, physical harm	0.6505
Clinical	Staff/Patient	134	Other medication interfering with this therapy	Undetected drug interference	Communication error, Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.3844
Clinical	Staff/Patient	55	Changing a patients posture or position interferes with the therapy	Interference with the therapy	Change in patients posture or position	Incorrect or inadequate therapy, discomfort, physical harm	0.2009

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Staff/Patient	28	Communication failures between clinician and patient during an examination	Incorrect or incomplete information or diagnosis	Misunderstanding between doctor and patient	Incorrect or inadequate therapy, discomfort, physical harm	0.0590
Clinical	Staff/Patient	56	Preparing a patient for transfer interferes with the therapy	Interference with the therapy	Preparation for transfer	Incorrect or inadequate therapy, discomfort, physical harm	0.2353
Clinical	Staff/Patient	57	Moving a patient between bed and chair causes interference with the therapy	Interference with the therapy	Transferring a patient between bed and chair	Incorrect or inadequate therapy, discomfort, physical harm	0.2659
Clinical	Staff/Patient	139	Bed spaces are in close proximity	Confusion with therapies common to two patients in close proximity	Proximity of bed spaces, Poor ward layout, Patient management error, Ward management error, Central bed management error	Reduced access, Increased possibility of wrong patient incidents (e.g. wrong patients flow rate adjusted)	0.1207
Clinical	Staff/Patient	49	Failure to detect patient entanglement in oxygen tubing	Undetected patient entanglement	Lack of vigilance	Impaired therapy, physical harm	0.1951
Clinical	Staff/Patient	200	Patient left unattended	Unattended patient on an oxygen cylinder	Human error, Organizational error, Process/protocol error	Undetected cylinder depletion, physical harm from accessories/tubing	
Clinical	Staff/Patient	158	Retrolental Fibroplasia	Oxygen overdose to neonate	Human error, Clinical error	Retrolental Fibroplasia, Permanent blindness	0.0113
Clinical	Staff/Patient	165	Clinical Error - Making decisions without reference to diagnostic results	Decisions made without reference to diagnostic results	Urgency, human error, delayed results	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff/Patient	205	Procedural delay - Examination	Delay in conducting an examination	Human error, lack of staff, Task overload, ward management failure, organizational failure	Delayed clinical decision or action	
Clinical	Staff/Patient	148	Incorrect management of patients with COPD	COPD	Incorrect therapy or wrong dose	CO2 retention, respiratory failure, Lack of oxygen if dose too low	0.1853
Clinical	Staff/Patient Monitoring	45	Failure to respond to or implement patient monitoring	Undetected therapy failure	Patient monitoring error through failure to act	Incorrect or inadequate therapy, discomfort, physical harm	0.1472
Clinical	Staff/Patient Monitoring	35	Mistakes or equipment failures when changing from portable to installed monitoring or vice-versa	Ineffective patient monitoring	Human error or equipment failure when changing between monitoring devices	delayed or ineffective monitoring	0.0525
Clinical	Staff/Patient Monitoring	43	Human error by clinical staff when monitoring patients	Undetected therapy failure	Lack of vigilance through patient monitoring error	Incorrect or inadequate therapy, discomfort, physical harm	0.1233
Clinical	Staff/Therapeutic Subsystem	215	Unsuitable running repairs	Inappropriate running repairs done to therpay system	Equipment fault, Lack of available replacements, procedure/process error, lack of knowledge/skill	Unreliable therapy, physical harm	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Staff/Therapeutic Subsystem	192	Interference from nursing tasks - Accidental therapy disconnection	Accidental disconnection at any point in the therapy system	Human error, loose connections	Sudden loss of therapy	
Clinical	Staff/Therapy Monitoring	131	Incorrect action when responding to or implementing patient monitoring	Incorrect action	Human error, Lack of Knowledge / Skill	Reduced patient monitoring, Impaired vigilance, Incorrect or inadequate therapy, discomfort, physical harm	0.2582
Clinical	Staff/Therapy Setup	191	Insufficient cylinder contents for transfer	Insufficient cylinder contents for transfer	Contents not checked before transfer, replacement cylinder not ordered in time	Cylinder depletion during transfer	
Clinical	Staff/Therapy Setup	176	Distraction of staff - Issue with this therapy puts other patients at risk	Staff are distracted by dealing with a problem with oxygen therapy	Human error, lack of staff, Task overload, ward management failure, organizational failure	Sub-optimal patient care, Inconsistent patient care, Inappropriate action, inadequate or no therapy	
Clinical	Staff/Therapy Setup	169	Contamination hazard - Used accessories not disposed of and replaced	Accessories used by a previous patient left at the bed space	Human error, lack of staff, Task overload, ward management failure, organizational failure	Cross-infection	
Clinical	Staff/Therapy Setup	136	Therapy not set up according to prescription or treatment order	Undetected setup error	Communication error, Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.3441
Clinical	Staff/Therapy Setup	154	Delayed Action from Staff	Delay in specifying, applying or adjusting therapy	Lack of staff or busy environment	Hypoxia, distress, discomfort	0.0073
Clinical	Staff/Therapy Setup	183	Equipment not checked	Equipment placed into storage for re-use or taken for use without being checked	Human error, lack of staff, Task overload, ward management failure, organizational failure	Unreliable, malfunctioning or contaminated equipment used on a patient	
Clinical	Therapy Monitoring	40	Failure to respond to an equipment alarm or warning	Undetected therapy failure	Lack of vigilance through unattended alarms or equipment notifications	Incorrect or inadequate therapy, discomfort, physical harm	0.1164
Clinical	Therapy Monitoring	48	Failure of therapy monitoring to detect a therapy disconnection	Undetected therapy disconnection	Ineffective patient monitoring	No therapy	0.1225
Clinical	Therapy Monitoring	50	Failure to detect cylinder depletion when in use	Undetected cylinder depletion	Lack of vigilance or information	No therapy	0.2651
Clinical	Therapy Monitoring	62	Failure to detect that the therapy has terminated early	Undetected therapy termination	Therapy monitoring	No therapy, discomfort, physical harm	0.3011
Clinical	Therapy Monitoring	54	Failure to notice an incorrectly positioned accessory	Misplaced accessory	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm	0.2151
Clinical	Therapy Monitoring	120	Failure by clinical staff to notice a patient disconnection	Undetected therapy disconnection	Lack of vigilance	No therapy	0.1363

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Therapy Monitoring	129	Failure to respond to or implement therapy monitoring	Undetected therapy failure	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.2816
Clinical	Therapy Monitoring	2	Failure to recognize and act on an imminent therapy failure	Therapy failure (Undetected)	Lack of vigilance, knowledge or Skill	Incorrect, Inadequate or No Therapy	0.0254
Clinical	Therapy Setup	15	Wrong type of accessory used for a particular therapy setup	Wrong accessory for purpose	Human error, lack of knowledge/skill, Correct accessory not available	Incorrect or inadequate therapy, discomfort, physical harm	0.4287
Clinical	Therapy Setup	36	Equipment improperly checked	Unreliable equipment	Human error: Equipment checks	Unreliable therapy or monitoring	0.1525
Clinical	Therapy Setup	60	Incorrect actions during patient transfer	Protocol/procedure error: Incorrect action	Transferring a patient between wards/departments	Incorrect or inadequate therapy, discomfort, physical harm	0.4551
Clinical	Therapy Setup	53	Accessory incorrectly administered or moved into an incorrect position by clinical staff	Misplaced accessory	Staff actions	Incorrect or inadequate therapy, discomfort, physical harm	0.2209
Clinical	Therapy Setup	113	A change of accessory is incorrectly implemented	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.4538
Clinical	Therapy Setup	126	Wrong type of accessory used for a particular therapy setup	Use error	Lack of Knowledge or Skill	Limited, interrupted, Incorrect or No Therapy	0.1723
Clinical	Therapy Setup	123	Therapy incorrectly or inappropriately set up when re-administered after a previous termination	Undetected incorrect or inappropriate therapy re-administration	Re-administering the therapy after a previous termination	Incorrect or inadequate therapy, discomfort, physical harm	0.2653
Clinical	Therapy Setup	122	Flow rate incorrectly or inappropriately adjusted	Dosage error	Human error, Lack of Knowledge / Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.3736
Clinical	Therapy Setup	121	Failure to detect a setup error	Undetected setup error	Lack of vigilance	Incorrect or inadequate therapy, discomfort, physical harm	0.2503
Clinical	Therapy Setup	119	Change either way between piped supply and cylinder incorrectly implemented	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.1613
Clinical	Therapy Setup	207	Setup - Oxygen not turned on	Oxygen supply not turned on at setup	Human error, lack of knowledge/skill, Communication error	No therapy	
Clinical	Therapy Setup	117	An incorrect adjustment is made to the therapy	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.2081
Clinical	Therapy Setup	107	Mistakes in setting up the therapy	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.2766

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Clinical	Therapy Setup	105	A factor relating to design within the therapy or the environment causes setup error	Undetected setup error	Human factors: Difficulty in administering therapy	Incorrect or inadequate therapy, discomfort, physical harm	0.1300
Clinical	Therapy Setup	202	Pressure/Abrasion sores from accessories	Poorly fitting accessories left in place too long	Human error, setup error, Therapy management error	Pressure sores or abraisions	
Clinical	Therapy Setup	137	A human factors issue with any equipment causes a functional failure because Equipment is applied differently to its intended use	Incorrect application of equipment	Equipment use error	Limited, interrupted, Incorrect or No Therapy	0.2093
Clinical	Therapy Setup	208	Setup error - Venturi mask	Flow rate does not match venturi specification	Human error, lack of knowledge/skill	Inadequate therapy	
Clinical	Therapy Setup/Supply	212	Transport without oxygen	Patients who require oxygen therapy are transported/transferred without	Human error, lack of knowledge/skill, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	Hypoxia, distress, discomfort	
Clinical	Therapy Setup/Supply	218	Wrong wall port - Suction instead of oxygen	Patient connected to suction port instead of oxygen	lack of knowledge/skill, Human error, procedure/protocol error	Hypoxia, physical harm, distress	
Supply	All	108	Undetected failed oxygen supply	Undetected supply failure	Lack of vigilance and Wall port failure, flow meter fault, Pipeline and alarm system failure or cylinder depletion	Incorrect or inadequate therapy, discomfort, physical harm	0.2337
Supply	Cylinder	170	Cylinder damage - Incorrect positioning on trolley	Aluminium cylinder crushed or punctured by bed or trolley height adjustment	Cylinder incorrectly positioned	Explosion/high pressure discharge, leak, unexpected depletion	
Supply	Cylinder	179	Equipment missing - Cylinder	Cylinder not in expected position	human error, theft, lack of cylinders	Delayed or no therapy	
Supply	Cylinder	174	Cylinder Quality - New cylinder empty	Unused, sealed new cylinder is empty	Manufacturing error, leaking cylinder	Delayed or no therapy	
Supply	Cylinder	172	cylinder faulty - leaking	Leaking cylinder	Faulty valve, faulty regulator, cracked /punctured cylinder	Unexpected depletion	
Supply	Cylinder	180	Equipment missing - Cylinder key	No cylinder key available to turn on gas supply	human error, theft, lack of cylinder keys	Delayed or no therapy	
Supply	Cylinder	32.1	Position of cylinder at the bed side causes unknown cylinder contents	Unknown cylinder contents	Obscured view of cylinder	Unreliable therapy, undetected cylinder depletion	0.2409
Supply	Cylinder	32	Position of cylinder at the bed side causes Physical obstruction	Physical obstruction at the bed side	Badly positioned Cylinder	Delayed or impaired access to patient, physical harm	0.0671

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Supply	Cylinder	171	Cylinder Faulty - Cannot turn on gas	Cylinder valve cannot be opened	Dabaged nut or faulty valve	Delayed or no therapy	
Supply	Cylinder	152.1	Wrong cylinder used	Wrong gas	Human error when applying therapy, Different cylinders stored together	Hypoxia, poisoning	0.0176
Supply	Cylinder	32.2	Position of cylinders at the bed side causes patients movements to be restricted by tubing position	Patients movements restricted by tubing position	Cylinder too far from patient	Displaced accessory, discomfort	0.1718
Supply	Cylinder	151	Manual Handling - Cylinders	Heavy, awkward cylinders	Moving or lifting cylinders	Falling cylinders or injury to staff	0.0068
Supply	Cylinder	150	Cylinder management - Unsecured/Unrestrained	Unrestrained cylinders	Moving or bumping into the cylinder	Falling cylinder harming people, damaging equipment or the cylinder, sudden loss of therapy to patient	0.0160
Supply	Cylinder/External - Institutional	204	Procedural delay - Cylinder restocking	Delay in replacement of empty cylinders	Ward management error, procedure/process error, communication error, human error	Cylinders not available for use	
Supply	External - Infrastructure	147	Not enough oxygen outlets for the number of patients requiring therapy	Unavailability of piped oxygen outlets	Insufficient number of oxygen outlets	Cylinders have to be used, reducing the reliability of the therapy or patients must be moved to other wards. Major threats are: Inadequate, unreliable or no therapy due to insufficient capacity,	0.1154
Supply	External - Infrastructure	145	No provision for the safe and organized storage of oxygen cylinders	The chaotic storage of used and full cylinders together	Inadequate Storage	Full and used cylinders stored together on the wards leading to the increased possibility of selecting one without adequate content	0.2283
Supply	External - Infrastructure	140	Two or more patients sharing a wall port or cylinder	Confusion with therapies common to two patients in close proximity	Shared resources, Human error, Ward layout error, Patient management error	Increased possibility of wrong patient incidents (e.g. wrong patients flow rate adjusted), Faster cylinder depletion, Possible common failure (same failure affecting two patients)	0.2157
Supply	External - institutional	217	Ward management - Empty and full cylinders stored together	Empty and full cylinders stored together	Ward management error, procedure/process error, communication error, human error	Unexpected cylinder depletion, delayed therapy, no therapy	
Supply	External - Maintenance	196	Oil used on oxygen outlet	Oil used on the oxygen outlet or regulator components	Lack of Knowledge or Skill, maintenance tasks carried out by untrained staff	Fire or explosion	
Supply	Flow Regulation	186	Flow meter not properly attached to wall port	Improperly attached flow meter falling or being expelled out of wall port	Human error, faulty shraeder valve	Falling equipment hitting patients or staff, sudden loss of therapy	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Supply	Flow Regulation	157	Flow Meter Fault	Incorrect indication of flow rate	Mechanical fault	Incorrect therapy	0.0037
Supply	Flow Regulation	181	Equipment missing - Flow meter	Flow meter missing from wall outlet or cylinder	human error, theft, lack of flow meters	Delayed or no therapy	
Supply	Piped	152	Wrong Gas port used	Wrong gas	Human error when applying therapy	Hypoxia, poisoning	0.0193
Supply	Piped	166	Collision between patient and pipeline outlet hardware	Patients colliding with therapy outlet hardware	Patient movements, posture/position changes, patient transfers	Physical harm	
Supply	Piped	168	Contaminated pipeline	Contaminants in oxygen pipeline	Ingress at a puncture, particles or chemicals from maintenance tasks	Hypoxia, poisoning	
Supply	Pressure Regulation	163	Regulator Faults	Faulty pressure reducing regulator on a cylinder	Mechanical fault	Low pressure, High pressure, Incorrect or inadequate therapy, discomfort, physical harm	0.0027
Supply	Pressure Regulation	182	Equipment missing - Regulator	Regulator missing from cylinder	human error, theft, lack of regulators, not swapped over on cylinder replacement	Delayed or no therapy	
Supply	Pressure Regulation	199	Oxygen Regulator Fire	Fire or explosion of oxygen regulator	Manufacturing error, Maintenance error, Oil/debris ingress	Fire, High speed projectiles, percussive bang, damaged equipment, physical harm to people in proximity, sudden loss of therapy	
Therapeutic	All	178	Equipment design issue	Confusing or difficult to use equipment	Design error or insuficient attention to human factors	Setup or use error, Sub-optimal patient care, Inconsistent patient care, Inappropriate, inadequate or no therapy	
Therapeutic	All	198	Oxygen flow impeded - Accessory blocked	Occluded accessory	Debris or deposits, Manufacturing error, setup error	No oxygen flow	
Therapeutic	External - Environment	42	Environmental issues like noise or cramped space cause visitors actions to interfere with the therapy	Interference/tampering with the therapy	Visitors actions when reacting to the environment	Incorrect or inadequate therapy, discomfort, physical harm, distraction of staff	0.0199
Therapeutic	External - Institutional	99	A lack of available equipment for therapy administration or monitoring	Lack of Equipment	Management error, Purchasing/stores error	Sub-optimal or ineffective therapy, No therapy	0.1652
Therapeutic	External - Institutional, Humidifier	193	Lack of resources; sterile water for humidifiers	No sterile water available for humidifiers	Resource management error, Central stores stock error	No humidification, non sterile water used resulting in an infection hazard	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Therapeutic	External - Person	3	Unauthorized or inappropriate action by others	Inappropriate or incorrect action - unauthorized person	Lack of vigilance, Visitor management failure, unrestricted access	Incorrect, Inadequate or No Therapy, discomfort, physical harm, distracted staff	0.0018
Therapeutic	External - Person	10	Innocent action by visitor to aid patient comfort compromises this therapy	Incorrect action by an unauthorized person	Therapy parameters are changed by uninformed action by visitor when patient or equipment is moved	Reduced or interrupted therapy or no therapy if undetected. Distracted staff.	0.0419
Therapeutic	Humidifier	187	Humidifier use error - Refilled with saline	Humidifier refilled with saline	Human error, lack of knowledge/skill	Salt deposits blocking humidifier	
Therapeutic	Humidifier	98	Humidifier incorrectly set up, used inappropriately or not used when it should	Humidification error	Lack of procedure/protocol, Lack of knowledge/skill, Human factors, Lack of equipment	Incorrect or inadequate therapy, discomfort, physical harm	0.2108
Therapeutic	Humidifier	184	Faulty humidifier	Humidifier does not provide the correct level of humidification or dispenses an incorrect oxygen concentration	Mechanical fault	Incorrect therapy	
Therapeutic	Humidifier	125	Undetected humidifier water depletion	Undetected humidifier water depletion	Lack of vigilance	Inadequate, unreliable or no therapy	0.1460
Therapeutic	Patient Connection	31	Spectacles or other obstructions on the face	Poorly fitting patient accessory	Spectacles or other obstructions on the face	Incorrect or inadequate therapy, discomfort, physical harm	0.1587
Therapeutic	Patient Connection	177	Endotracheal tube blocked	Blocked endotracheal tube	Setup error, debris	Hypoxia, distress, discomfort	
Therapeutic	Patient Connection	160	Tracheostomy Complications	Loose or blocked tracheostomy	Setup error, patient movement, debris	Hypoxia, distress, discomfort	0.0113
Therapeutic	Patient Connection	116	An accessory is incorrectly or inappropriately disconnected by clinical staff	Undetected accessory disconnection	Human error, Lack of Knowledge or Skill	Incorrect or inadequate therapy, discomfort, physical harm	0.4918
Therapeutic	Patient Connection	115	An accessory is displaced when a patient's position or posture is changed	Accessory displacement	Changing a patients posture or position	Incorrect or inadequate therapy, discomfort, physical harm	0.2168
Therapeutic	Patient Connection	101	Failure to correct a displaced accessory	Misplaced accessory	Failure to act	Incorrect or inadequate therapy, discomfort, physical harm	0.2038
Therapeutic	Patient Connection	90	The accessory has to be changed to relieve patient discomfort	Unsuitable accessory	Accessory causes discomfort	Patient removes accessory to relieve discomfort	0.1206
Therapeutic	Patient Connection	67	Accessory moved into an incorrect position by Patient	Misplaced accessory	Patients actions	Incorrect or inadequate therapy, discomfort, physical harm	0.2688

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Threats/Effects	Risk
Therapeutic	Patient Connection	37	Physical failure of a patient connected accessory	Undetected accessory failure	Any physical or functional failure of any accessory	Limited or complete lack of therapy	0.1326
Therapeutic	Tubing	118	Bubble tubing incorrectly cut	Undetected setup error	Human error	Incorrect or inadequate therapy, discomfort, physical harm	0.0901
Therapeutic	Tubing	213	Tubing damaged - Melted due to contact with hot surface	Contact between tubing and hot surfaces	Tubing routing error, Patient movements or actions	Fire, oxygen leak, ineffective therapy, inhalation of smoke/vapour	
Therapeutic	Tubing	110	Therapy tubing disconnected in error	Undetected tubing disconnection	Inappropriate or inadvertent action	No therapy	0.4555
Therapeutic	Tubing	189	Infection risk - Fungus in oxygen tubing	Fungal growth in oxygen tubing	Non-sterile water in humidifier, tubing in use for too long	Respiratory infection	
Therapeutic	Tubing	34	Tubing pinched in furniture or other equipment at the bed side	Damaged or occluded tubing	Poor tubing position	Possible undetected tubing disconnection, occlusion or cutting causing a loss or reduction of therapy or an oxygen leak.	0.0908

	Mean	0.1663
	1.5 times the Mean	0.2494
	0.5 times the Mean	0.0831

Risk Key:		
	High	> 0.2494
	Moderate	> 0.1663 < 0.2494
	Minor	> 0.0831 < 0.1663
	Low	< 0.0831

Appendix E The Formal Hazard Analyses.

E.1 Failure Modes and Effects Analysis.

Table Appendix E.1-1 The Failure Modes and Effects Analysis of ward based Oxygen Therapy.

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
1.1. Piped Supply	1.1.1. No Supply	No gas, Pipeline damaged, Maintenance	Alarm panel	1.1.1a Therapy cannot be set up	6	2	1	12	0.033	0.003	0.030	0.193
				1.1.1b Supply fails during use	6	2	1	12	0.033			
				1.1.1c Change to cylinders	2	2	1	4	0.011			
				1.1.1d Transfer to another ward	2	2	1	4	0.011			
	1.1.2. Contamination	Residue from maintenance, Substance ingress due to damage, Backflow from devices	None	1.1.2a Poisoning	6	2	10	120	0.333	0.012		
				1.1.2b Change to cylinders	2	2	1	4	0.011			
				1.1.2c Transfer to another ward	2	2	1	4	0.011			
	1.1.3. No Ports Available	Insufficient capacity, Overpopulated ward	Planning	1.1.3a Therapy cannot be set up	6	4	2	48	0.133	0.006		
				1.1.3b Change to cylinders	2	4	1	8	0.022			
				1.1.3c Transfer to another ward	2	4	1	8	0.022			
	1.1.4. Wrong Gas Administered	Human error	Visual	1.1.4a Hypoxia	5	2	8	80	0.222	0.008		
				1.1.4b Delayed therapy	2	2	1	4	0.011			
	1.1.5. Port Connector Failure	Wear, Damage	Visual	1.1.5a Flow meter will not attach	2	2	1	4	0.011	0.001		
				1.1.5b Flow meter is expelled during use	2	1	2	4	0.011			
1.2. Cylinder Supply	1.2.1. Wrong Gas	Human error	None	1.2.1a Hypoxia	5	3	8	120	0.333	0.012	0.049	
				1.2.1b Delayed therapy	2	3	1	6	0.017			
	1.2.2. Empty	Leaking, Incorrect	Pressure gauge	1.2.2a Therapy cannot be set up	5	4	1	20	0.056	0.018		

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
		Pressure Indication		1.2.2b Therapy fails during use	5	4	8	160	0.444			
				1.2.2c Delayed therapy	2	4	1	8	0.022			
	1.2.3. No cylinders Available	No Central Stock, Ward management error	Ward management	1.2.3a Therapy cannot be set up	5	2	2	20	0.056	0.002		
				1.2.3b Delayed therapy	2	3	1	6	0.017			
	1.2.4. Cylinder Valve Shut	Human error, No Key	Ward management	1.2.4a Therapy cannot be set up	5	2	8	80	0.222	0.008		
				1.2.4b Delayed therapy	2	4	1	8	0.022			
	1.2.5. Falling Cylinder	Unsecured	Visual	1.2.5a Cylinder falls when moved	3	3	5	45	0.125	0.008		
				1.2.5b Cylinder falls when bumped	3	3	5	45	0.125			
1.3. Pressure Regulator	1.3.1. Incorrect Gas Type	Human error	None	1.3.1a Fire due to contaminants	5	1	8	40	0.111	0.009	0.053	
				1.3.1b Will not fit on cylinder	2	2	2	8	0.022			
				1.3.1c Incorrect pressure output	3	2	8	48	0.133			
	1.3.2. Incorrect Connector Type	Human error	Visual	1.3.2a Accessories will not fit	2	4	5	40	0.111	0.004		
	1.3.3. No Regulators Available	Equipment Management Error	Ward management	1.3.3a Therapy cannot be set up	5	2	2	20	0.056	0.003		
				1.3.3b Delayed therapy	2	3	2	12	0.033			
	1.3.4. Pressure gauge reading Low	Mechanical Fault	None	1.3.4a Cylinder replaced early	1	4	10	40	0.111	0.004		
	1.3.5. Pressure gauge reading High	Mechanical Fault	None	1.3.5a Unexpected depletion	5	4	10	200	0.556	0.019		
	1.3.6. Leaking	Mechanical Fault	Audible/Visible	1.3.6a Cylinder depletes before expected	5	4	8	160	0.444	0.015		
1.4. Flow Regulator	1.4.1. Incorrect Gas Type	Human Error	Visual	1.4.1a Fire due to contaminants	4	1	2	8	0.022	0.001	0.062	
				1.4.1b Incorrect flow reading	2	1	2	4	0.011			
	1.4.2. No Flow meters Available	Equipment Management Error	Ward management	1.4.2a Therapy cannot be set up	5	2	2	20	0.056	0.003		
				1.4.2b Delayed therapy	2	4	2	16	0.044			
	1.4.3. Wrong flow range	Human Error,	Visual	1.4.3a Flow rate too high	4	3	2	24	0.067	0.006		

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
		Not obviously distinctive, All stored together		1.4.3b Flow rate too low	4	3	2	24	0.067			
				1.4.3c Delayed therapy	2	4	2	16	0.044			
	1.4.4. Incorrect Outlet Connector	Human Error	Visual	1.4.4a Therapy cannot be set up	5	3	5	75	0.208	0.011		
				1.4.4b Delayed therapy	2	4	5	40	0.111			
	1.4.5. Inaccessible while in use	Environmental factor, Human Error	Visual	1.4.5a Flow rate unknown	3	4	5	60	0.167	0.010		
				1.4.5b Flow rate cannot be changed	3	3	5	45	0.125			
	1.4.6. Leaking When Turned Off	Mechanical Fault	Audible	1.4.6a Cylinder depletes in storage	2	4	8	64	0.178	0.006		
	1.4.7. Flow Reading Low	Mechanical Fault	None	1.4.7a Too much oxygen	4	2	10	80	0.222	0.017		
				1.4.7b Cylinder depletes before expected	5	2	10	100	0.278			
	1.4.8. Flow Reading High	Mechanical Fault	None	1.4.8a Too little oxygen	4	2	10	80	0.222	0.008		
2.1. Choice (Humidifier)	2.1.1. No Protocol	Institutional Error	Ward management	2.1.1a Humidifier used when not required	2	3	5	30	0.083	0.011	0.089	0.448
				2.1.1b Humidifier not used when required	3	6	5	90	0.250			
	2.1.2. Incorrect Protocol	Human error	Review	2.1.2a Humidifier used when not required	2	3	8	48	0.133	0.011		
				2.1.2b Humidifier not used when required	3	3	8	72	0.200			
	2.1.3. Protocol not Applied	Human Error, Complacency	Visual	2.1.3a Humidifier used when not required	2	3	8	48	0.133	0.014		
				2.1.3b Humidifier not used when required	3	4	8	96	0.267			
	2.1.4. No Information for Decision	Human Error, Missing Notes	Procedural	2.1.4a Therapy set up with low flow so that humidifier is not required	4	4	5	80	0.222	0.016		
				2.1.4b Therapy set up with high flow, humidified	3	2	5	30	0.083			
				2.1.4c Therapy set up with low flow and humidifier applied	4	1	5	20	0.056			
				2.1.4d Therapy set up with high flow, not humidified	2	4	5	40	0.111			

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
	2.1.5. Incorrect Information	Human Error	None	2.1.5a Humidifier used when not required	2	2	10	40	0.111	0.018		
				2.1.5b Humidifier not used when required	3	5	10	150	0.417			
	2.1.6. Decision by untrained person	Institutional Error	Review of notes	2.1.6a Humidifier used when not required	2	2	8	32	0.089	0.010		
				2.1.6b Humidifier not used when required	3	3	8	72	0.200			
	2.1.7. Incorrect decision	Human Error	Re-examination	2.1.7a Humidifier used when not required	2	2	8	32	0.089	0.010		
				2.1.7b Humidifier not used when required	3	3	8	72	0.200			
2.2. Humidifier	2.2.1. No Humidifiers Available	Central Supplies failure, Ward Management Error	Ward management	2.2.1a Therapy not applied	5	2	2	20	0.056	0.009	0.054	
				2.2.1b Delayed therapy	4	3	2	24	0.067			
				2.2.1c Therapy set up with low flow so that humidifier is not required	4	4	2	32	0.089			
				2.2.1d Therapy set up with specified flow, not humidified	3	4	2	24	0.067			
	2.2.2. Connections loose	Equipment Failure, Human Error	None	2.2.2a Undetected disconnection	5	2	10	100	0.278	0.009		
	2.2.3. Connections leaking	Equipment Failure, Human Error	None	2.2.3a Incorrect delivered flow	4	3	10	120	0.333	0.011		
	2.2.4. Water level low	Human Error	Visual	2.2.4a Unhumidified therapy	2	4	2	16	0.044	0.002		
	2.2.5. Flow too high for Concentration setting	Human Error, Use Error	Visual	2.2.5a Oxygen concentration higher than set value	2	4	5	40	0.111	0.004		
	2.2.6. Flow too low for concentration setting	Human Error, Use Error	Visual	2.2.6a Lower than set concentration	4	4	5	80	0.222	0.008		
	2.2.7. Humidifier inaccessible	Environmental factor, Human Error	Visual	2.2.7a Adjustments cannot be made	4	3	5	60	0.167	0.008		
				2.2.7b Maintenance cannot be carried out	2	3	5	30	0.083			

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
	2.2.8. Humidifier not visible	Environmental factor, Human Error	Visual	2.2.8a Status cannot be monitored	2	3	5	30	0.083	0.003		
2.3. Tubing	2.3.1. Correct tubing not available	Central Supplies failure, Ward Management Error	Ward management	2.3.1a Therapy not applied	5	2	2	20	0.056	0.007	0.115	
				2.3.1b Delayed therapy	4	3	2	24	0.067			
				2.3.1c Incorrect type used	5	3	2	30	0.083			
	2.3.2. Incorrect type / Diameter used	Human Error	Visual	2.3.2a Insufficient flow rate	4	3	5	60	0.167	0.013		
				2.3.2b Water from humidifier trapped	5	3	5	75	0.208			
	2.3.3. Tubing too long	Human Error, Stock Error	Visual	2.3.3a Excess tubing snagging	2	3	5	30	0.083	0.017		
				2.3.3b Patient entanglement	3	3	5	45	0.125			
				2.3.3c Untidy bed space	2	3	5	30	0.083			
				2.3.3d Unsafe routing	5	3	5	75	0.208			
	2.3.4. Tubing too short	Human Error, Stock Error	Visual	2.3.4a Patient discomfort	2	3	5	30	0.083	0.010		
				2.3.4b Unsafe routing	5	3	5	75	0.208			
	2.3.5. Unsafe routing	Human Error	Visual	2.3.5a Tubing damage	5	3	8	120	0.333	0.011		
	2.3.6. Connections loose	Human Error	None	2.3.6a Undetected disconnection	5	3	10	150	0.417	0.014		
	2.3.7. Connections leaking	Human Error	None	2.3.7a Incorrect delivered flow	4	3	10	120	0.333	0.011		
	2.3.8. Tubing ruptured	Human Error	audible	2.3.8a Incorrect delivered flow	4	3	8	96	0.267	0.009		
	2.3.9. Tubing squashed / pinched	Human Error	Visual	2.3.9a Reduced flow	5	3	8	120	0.333	0.011		
	2.3.10. Tubing occluded	Human Error	Visual	2.3.10a Reduced flow	5	3	8	120	0.333	0.011		
2.4. Choice (Nebuliser)	2.4.1. No Protocol	Institutional Error	None	2.4.1a Nebulizer used incorrectly	3	2	5	30	0.083	0.003	0.047	
	2.4.2. Incorrect Protocol	Human error	Review	2.4.2a Nebulizer used incorrectly	3	2	8	48	0.133	0.005		
	2.4.3. Protocol not Applied	Human error, Complacency	Visual	2.4.3a Nebulizer used incorrectly	3	2	8	48	0.133	0.005		
	2.4.4. No Information for Decision	Procedural Error, Human Error	None	2.4.4a Nebulised medication not administered	3	3	5	45	0.125	0.007		

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
				2.4.4b Nebulised medication wrongly administered	2	3	5	30	0.083			
	2.4.5. Incorrect Information	Procedural Error, Human Error	None	2.4.5a Nebulised medication not administered	3	3	8	72	0.200	0.011		
				2.4.5b Nebulised medication wrongly administered	2	3	8	48	0.133			
	2.4.6. Decision by untrained person	Institutional Error, Ward Management Error	Review	2.4.6a Nebulised medication not administered	3	2	8	48	0.133	0.008		
				2.4.6b Nebulised medication wrongly administered	2	2	8	32	0.089			
	2.4.7. Incorrect decision	Human Error	Re-examination	2.4.7a Nebulised medication not administered	3	2	5	30	0.083	0.005		
				2.4.7b Nebulised medication wrongly administered	2	2	5	20	0.056			
	2.4.8. Patient requirement incorrectly assessed	Human Error	Re-examination	2.4.8a Nebulised medication not administered	3	2	5	30	0.083	0.005		
				2.4.8b Nebulised medication wrongly administered	2	2	5	20	0.056			
2.5. Nebulizer	2.5.1. Flow rate too low	Human Error	Visual	2.5.1a Inefficient nebulisation	2	4	8	64	0.178	0.006	0.031	
	2.5.2. Flow rate too high	Human Error	Visual	2.5.2a Patient discomfort	2	5	5	50	0.139	0.009		
				2.5.2b Wasted medication	2	5	5	50	0.139			
	2.5.3. Incorrect medication type	Human Error	Dispensing Checks	2.5.3a Patient harm	5	2	2	20	0.056	0.004		
				2.5.3b Nebuliser occlusion	5	2	2	20	0.056			
	2.5.4. Nebulizer not available	Central Supplies failure, Ward Management Error	Ward management	2.5.4a Medication cannot be administered	2	3	2	12	0.033	0.001		
	2.5.5. Incorrectly attached	Human Error	Visual	2.5.5a No medication nebulised	2	3	5	30	0.083	0.008		
				2.5.5b No oxygen flow	5	2	5	50	0.139			

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
	2.5.6. Medication incorrectly applied	Human Error	Dispensing Checks	2.5.6a No medication nebulised	2	3	2	12	0.033	0.003		
				2.5.6b Too much medication administered	2	3	2	12	0.033			
				2.5.6c Too little medication administered	2	3	2	12	0.033			
2.6. Patient Connection	2.6.1. Wrong size face mask	Human Error, Stock Error	Visual	2.6.1a Patient discomfort	2	2	2	8	0.022	0.002	0.112	
				2.6.1b Inefficient therapy	3	2	2	12	0.033			
	2.6.2. Specs used on high flow	Human error	Visual	2.6.2a Patient discomfort	2	3	5	30	0.083	0.007		
				2.6.2b Nasal sinus damage	3	3	5	45	0.125			
	2.6.3. Face mask used on flow lower than recommended	Human Error, Use Error	Visual	2.6.3a CO2 from exhallation not expelled before next breath	3	5	8	120	0.333	0.011		
	2.6.4. Non-rebreathe mask with flow too low	Human Error, Use Error	Visual	2.6.4a Resevoire not fully replenished between breaths	3	4	5	60	0.167	0.006		
	2.6.5. Non-rebreathe bag with no flow	Human Error, Use Error	Visual	2.6.5a Increased effort of breathing	2	4	2	16	0.044	0.002		
				2.6.5b Suffocation	5	1	2	10	0.028			
	2.6.6. Inappropriate Position / Placement at setup	Human error,	Visual	2.6.6a Patient discomfort	2	2	5	20	0.056	0.009		
				2.6.6b Inefficient therapy	3	2	5	30	0.083			
				2.6.6c No therapy	5	2	5	50	0.139			
	2.6.7. Moved into inappropriate Position / Placement	Patient actions, Human error	Visual	2.6.7a Patient discomfort	2	6	8	96	0.267	0.034		
				2.6.7b Inefficient therapy	3	6	8	144	0.400			
				2.6.7c No therapy	5	3	8	120	0.333			
	2.6.8. Correct Accessory not Available	Central Supplies failure, Ward Management Error	None	2.6.8a Therapy not applied	5	2	2	20	0.056	0.005		
				2.6.8b Delayed therapy	2	4	2	16	0.044			
				2.6.8c Incorrect Acessory Used	2	4	2	16	0.044			
	2.6.9. Mask Split	Mechanical Fault, Mishandling	Visual	2.6.9a Patient discomfort	2	2	5	20	0.056	0.005		
				2.6.9b Inefficient therapy	3	2	5	30	0.083			
	2.6.10. Mask strap broken	Mechanical Fault, Mishandling	Visual	2.6.10a Mask cannot be fitted	2	4	5	40	0.111	0.009		
				2.6.10b Mask falls off	4	3	5	60	0.167			

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
	2.6.11. Specs Occluded	Nasal deposits, manufacturing fault, Twisted / Kinked	Visual	2.6.11a Therapy not applied	4	3	5	60	0.167	0.006		
	2.6.12. Mask Blocked	Deposits, manufacturing fault	None	2.6.12a Therapy not applied	5	2	5	50	0.139	0.005		
	2.6.13. Tracheostomy loose	Human Error, Manufacturing fault	Visual	2.6.13a Inefficient therapy	4	4	5	80	0.222	0.008		
	2.6.14. Tracheostomy Blocked	Deposits, manufacturing fault	Routine checks	2.6.14a Therapy not applied	5	4	2	40	0.111	0.004		
3.1. Patient	3.1.1. Condition changes	Multiple	Patient monitoring, Clinical examination, Patient report	3.1.1a Therapy becomes unsuitable	5	5	2	50	0.139	0.005	0.062	0.368
	3.1.2. Does not co-operate	Multiple	Visual	3.1.2a Therapy not possible	4	5	10	200	0.556	0.019		
	3.1.3. Cannot communicate	Multiple	Interview	3.1.3a Delayed therapy	4	4	2	32	0.089	0.003		
	3.1.4. Moves or removes mask	Multiple	Patient monitoring	3.1.4a Compromised therapy	5	4	8	160	0.444	0.015		
	3.1.5. Tampers with therapy settings	Boredom, Curiosity, attempt to relieve discomfort	Patient monitoring	3.1.5a Compromised therapy	5	3	8	120	0.333	0.011		
	3.1.6. Experiences discomfort	Multiple	Patient monitoring	3.1.6a Action taken compromises therapy	4	3	8	96	0.267	0.009		
3.2. Patient Monitoring	3.2.1. Equipment total failure	Multiple	Visual	3.2.1a No warnings of change to patient condition	5	4	5	100	0.278	0.009	0.046	
	3.2.2. Use error	Human error, Equipment design factor	None	3.2.2a No warnings of change to patient condition	5	4	8	160	0.444	0.015		
	3.2.3. Equipment not available	Multiple	Ward management	3.2.3a No patient monitoring	5	3	5	75	0.208	0.007		
	3.2.4. Incorrect information	Equipment error, Setup error	None	3.2.4a ineffective patient monitoring	5	3	10	150	0.417	0.014		

System Element	Failure Mode	Causes	Detection Methods	Effects	Severity	Likelihood	Detection	RPN	Proportional Risk	Failure Mode Proportional Risk	Element Risk	Subsystem Risk
3.3. Setup and Monitoring	3.3.1. Not set up according to specification	Human error, Parts unavailable	Visual	3.3.1a Unsuitable therapy	5	3	8	120	0.333	0.011	0.059	
	3.3.2. Therapy not applied	Human error, Communication error	Clinical review	3.3.2a No therapy	5	3	2	30	0.083	0.003		
	3.3.3. Therapy status not monitored	Human error, Procedural error	None	3.3.3a Unsuitable therapy	5	6	8	240	0.667	0.045		
				3.3.3b Undetected therapy failure	5	6	8	240	0.667			
3.4. Clinical Staff	3.4.1. Staff not available	Institutional and ward management	Management process	3.4.1a Delayed therapy	5	5	5	125	0.347	0.040	0.201	
				3.4.1b ineffective patient monitoring	5	6	5	150	0.417			
				3.4.1c Ineffective therapy management	5	6	5	150	0.417			
	3.4.2. Over tasked	Institutional and ward management	Management process	3.4.2a Delayed therapy	5	6	8	240	0.667	0.068		
				3.4.2b ineffective patient monitoring	5	6	8	240	0.667			
				3.4.2c Ineffective therapy management	5	6	8	240	0.667			
	3.4.3. Fail to communicate	process and procedural error, attitude	None	3.4.3a No therapy	5	4	8	160	0.444	0.026		
				3.4.3b clinical error	5	3	8	120	0.333			
	3.4.4. Insufficient knowledge / Skill	Lack of effective training, attitude	Ward management	3.4.4a Unsuitable therapy	5	4	5	100	0.278	0.019		
				3.4.4b compromised therapy	5	4	5	100	0.278			
	3.4.5. Diagnosis error	Multiple	Clinical review	3.4.5a Clinical error	5	3	2	30	0.083	0.012		
	3.4.6. Therapeutic requirement error	Multiple	Clinical review	3.4.6a No therapy	5	4	5	100	0.278	0.019		
				3.4.6b Unsuitable therapy	5	4	5	100	0.278			
	3.4.7. Therapy specification error	Human error	Review at setup	3.4.7a Unsuitable therapy	5	5	5	125	0.347	0.012		
	3.4.8. Therapy not specified	Human error, Procedural error	Clinical review	3.4.8a Therapy not applied, Unsuitable therapy	5	6	2	60	0.167	0.006		
	98				Total Risk			10645	29.569	1.009	1.009	1.009
					Average Risk			61.89	0.172	0.010	0.072	0.336

E.2 Fault Tree Analysis.

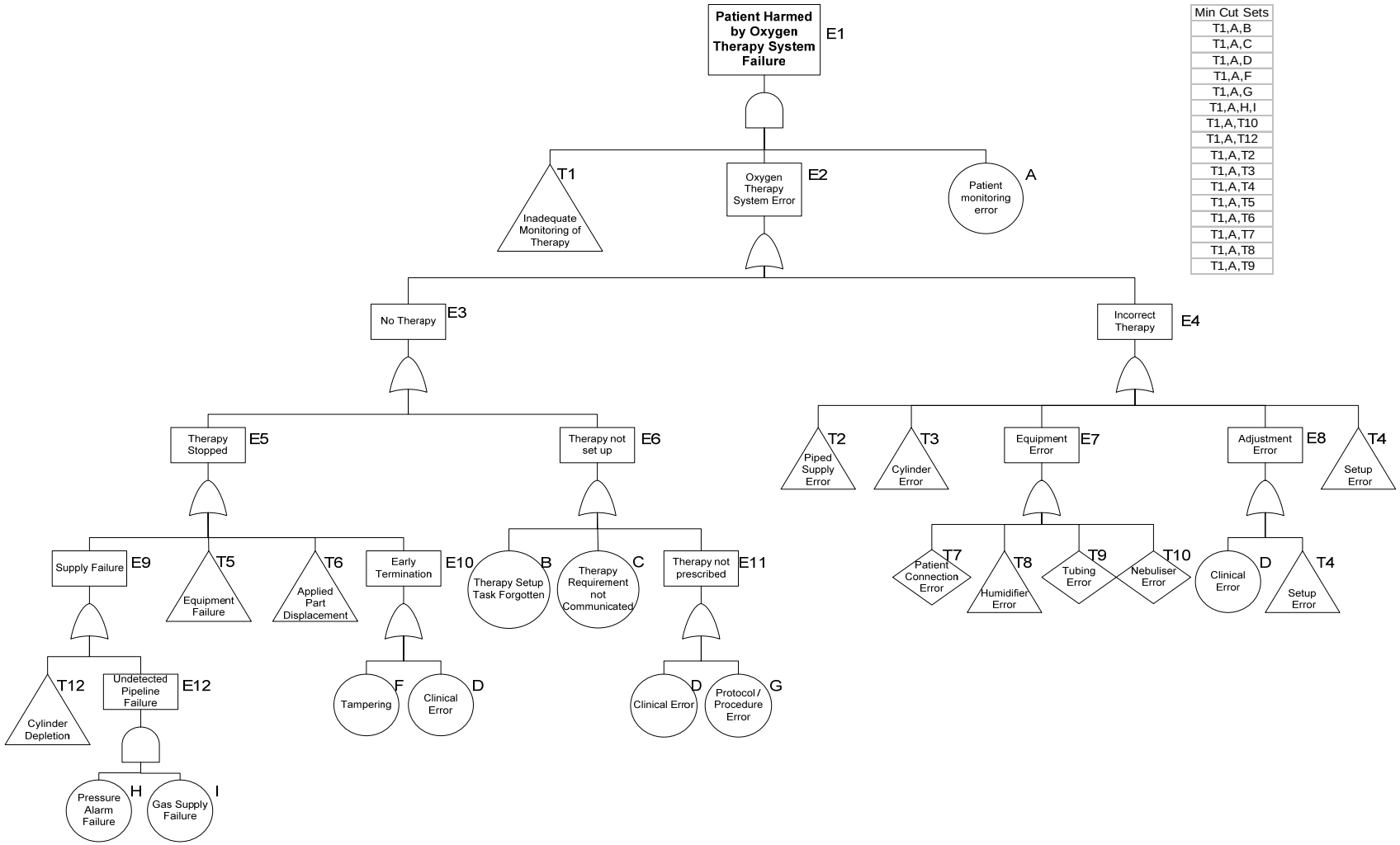


Figure Appendix E-1 Top Tree 1

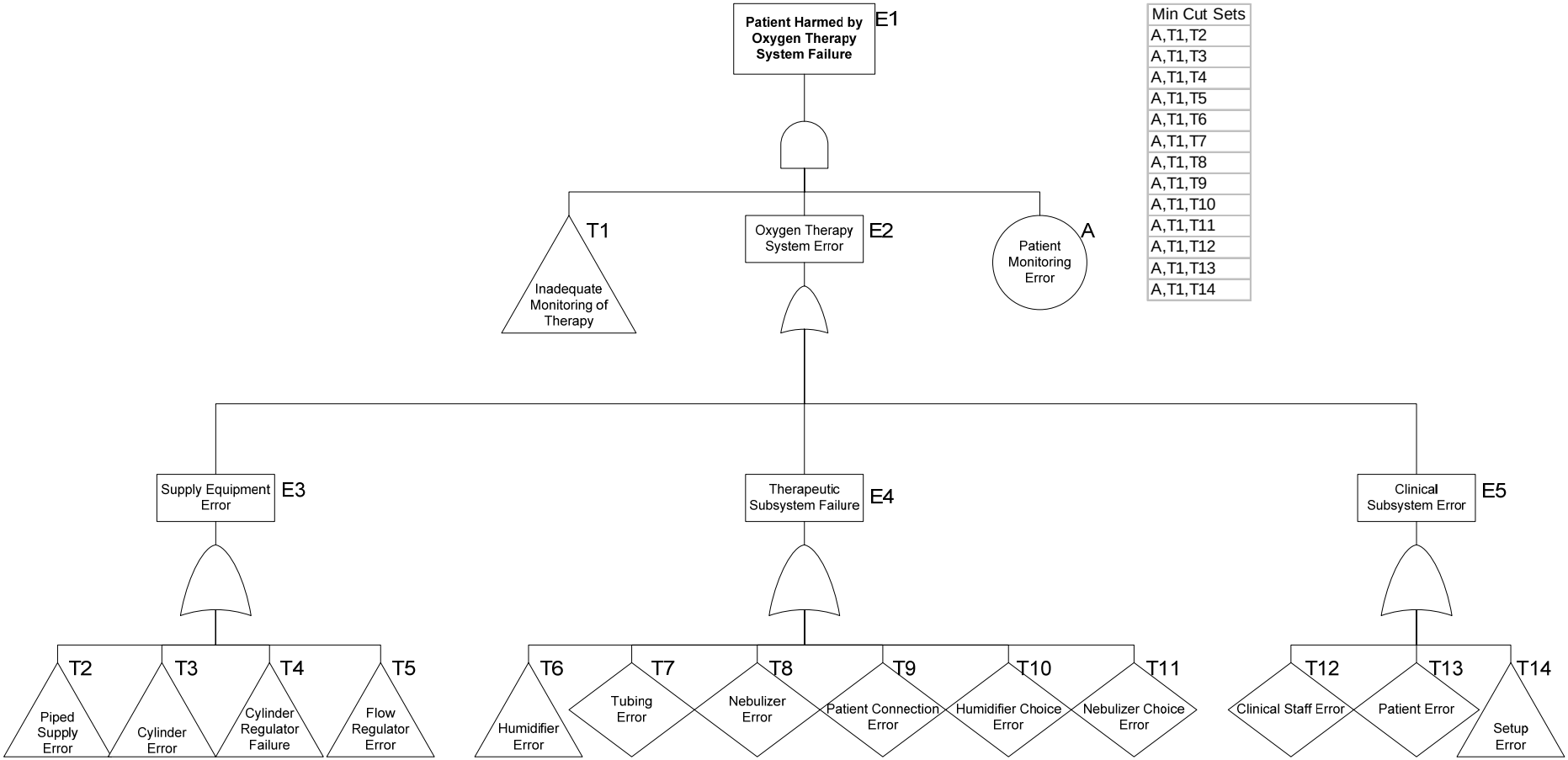
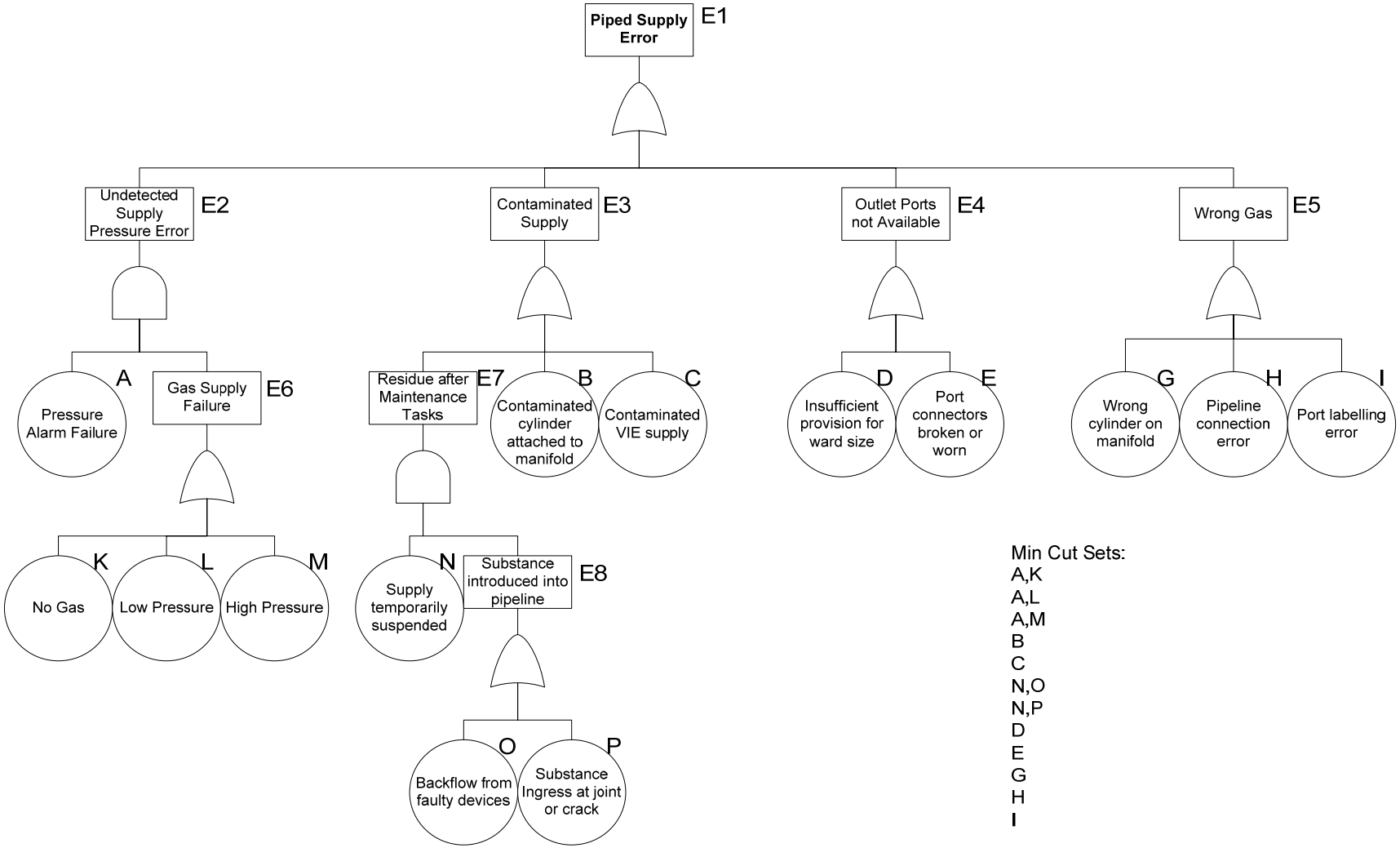


Figure Appendix E-2 Top Tree 2



Min Cut Sets:
A,K
A,L
A,M
B
C
N,O
N,P
D
E
G
H
I

Figure Appendix E-3 Piped Supply Error

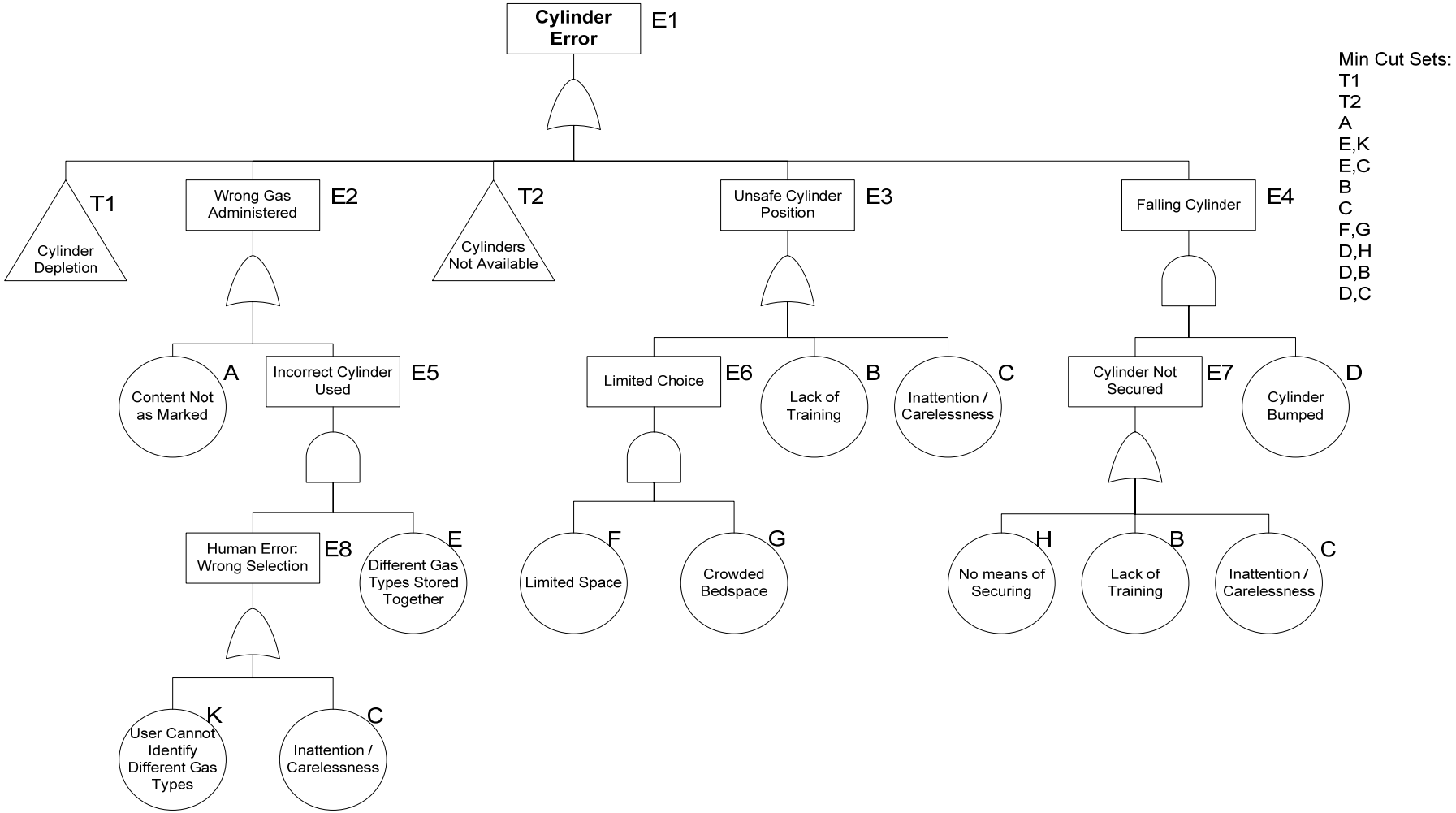


Figure Appendix E-4 Cylinder Error

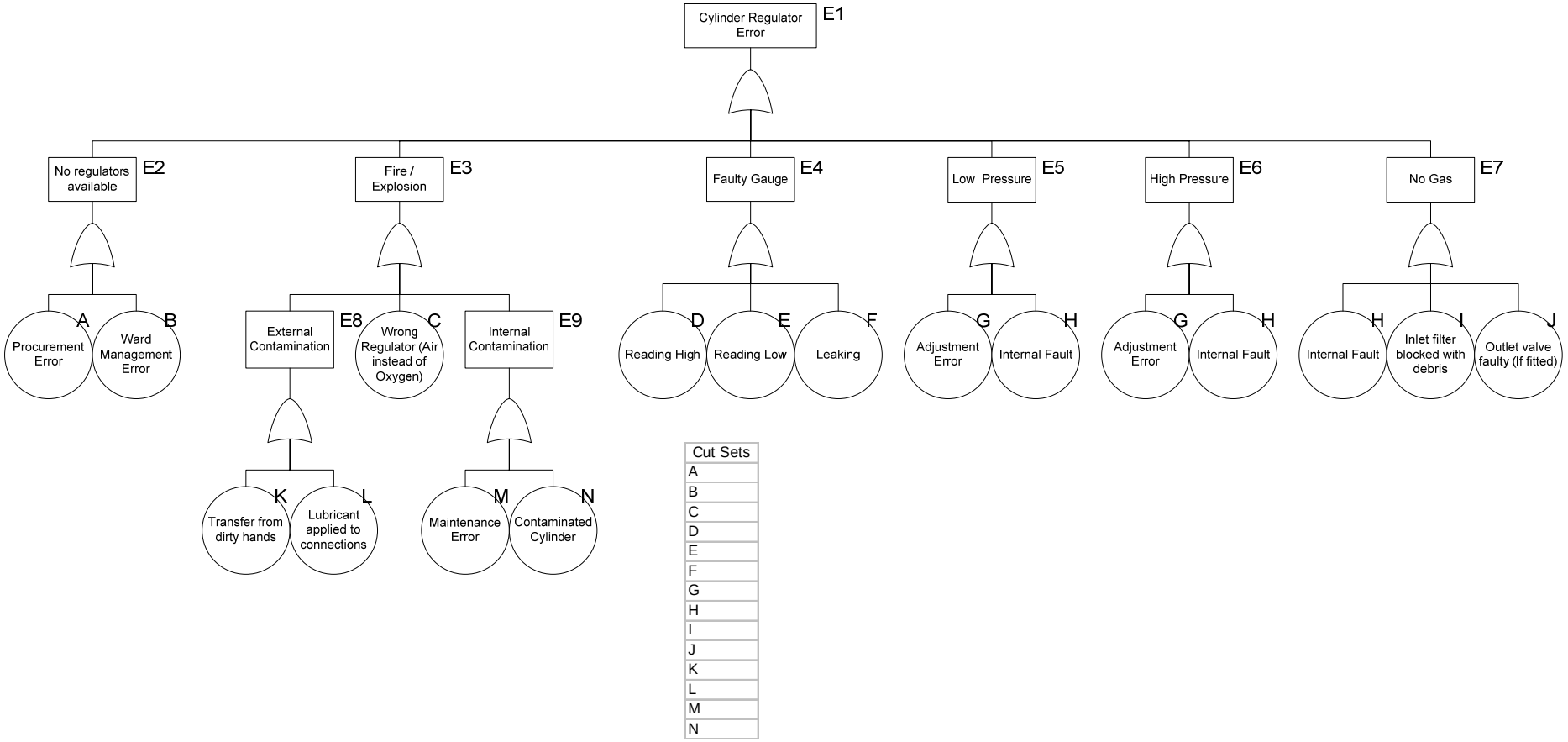


Figure Appendix E-5 Cylinder Regulator Error.

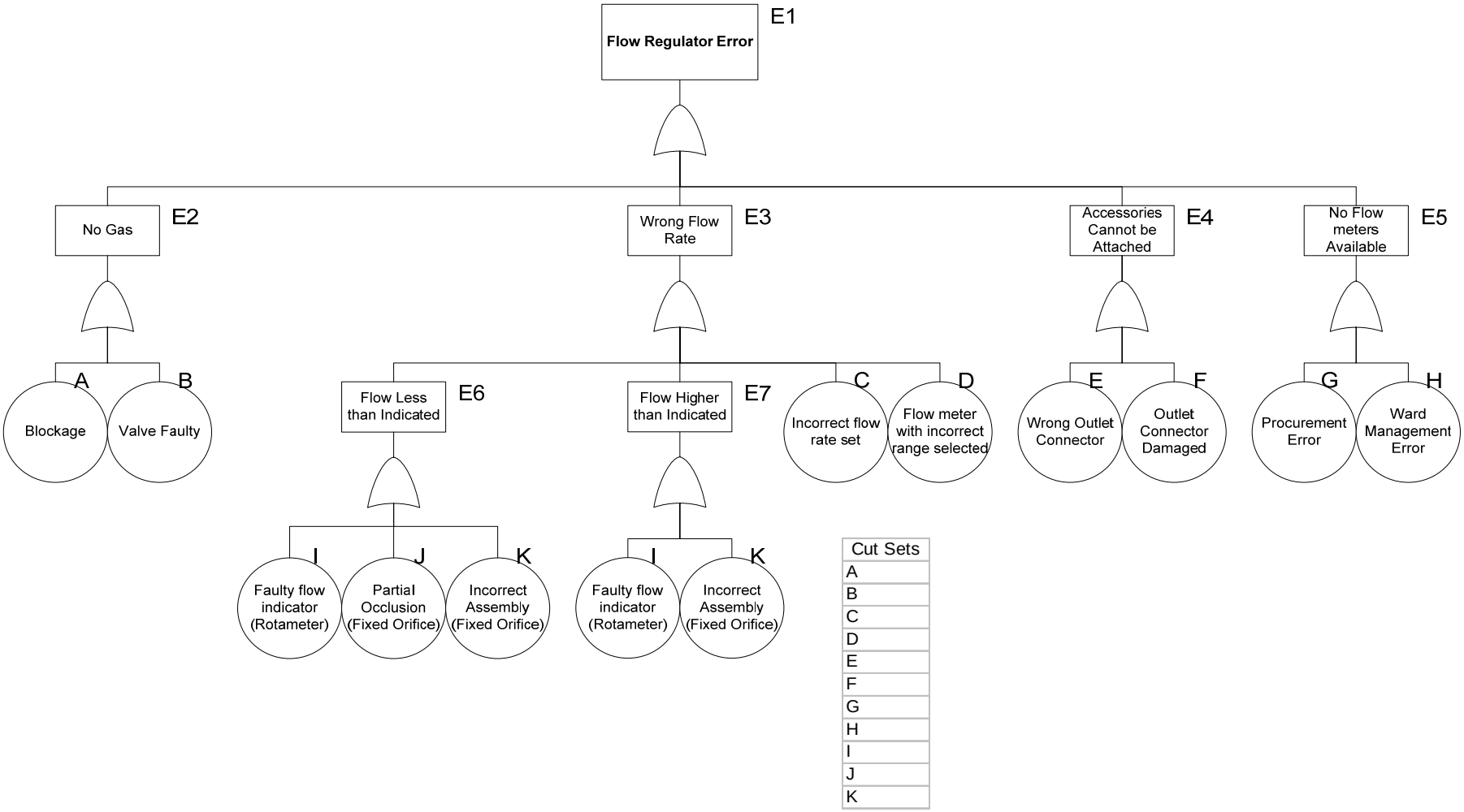
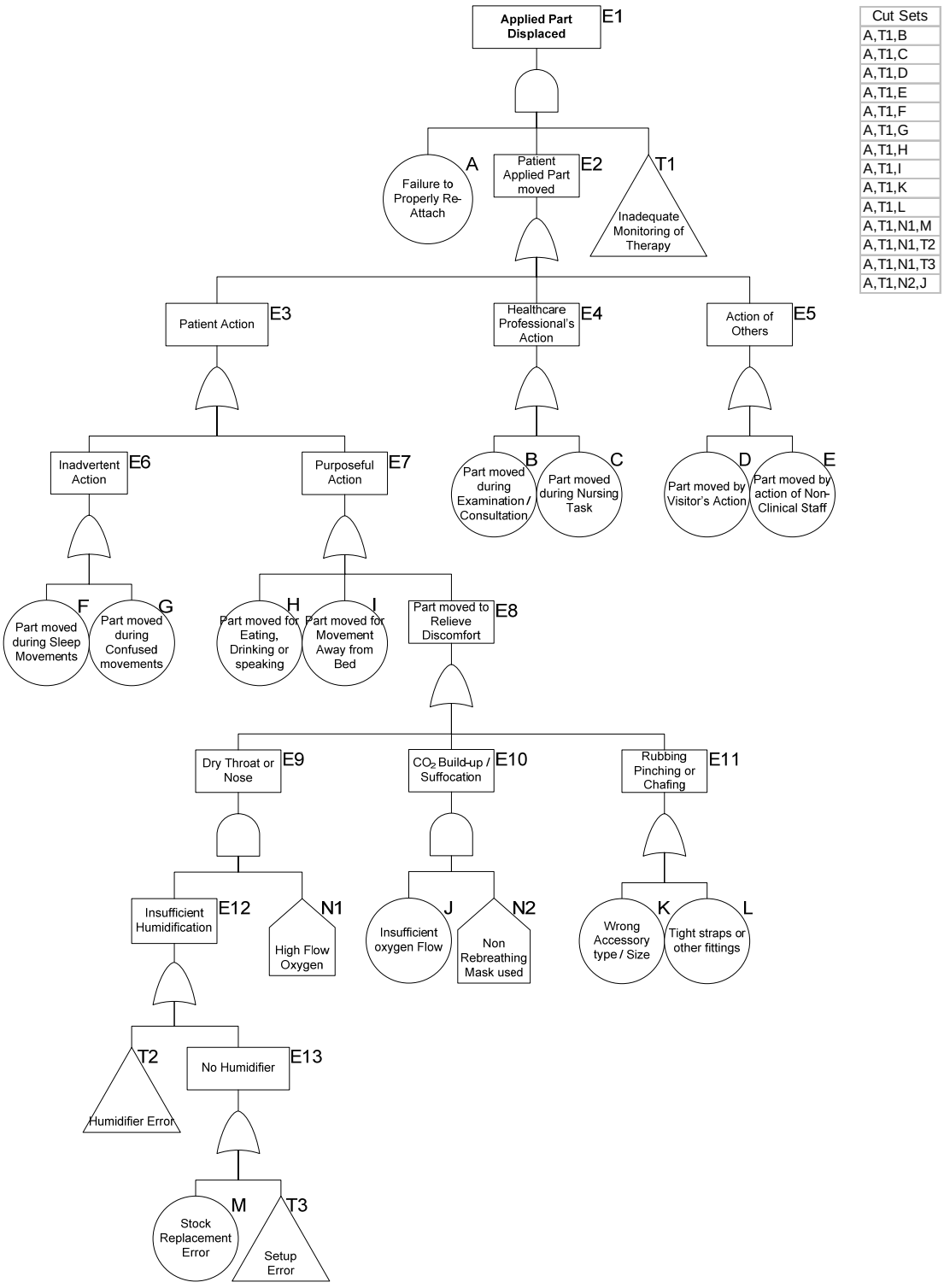


Figure Appendix E-6 Flow Regulator Error.



Cut Sets
A,T1,B
A,T1,C
A,T1,D
A,T1,E
A,T1,F
A,T1,G
A,T1,H
A,T1,I
A,T1,K
A,T1,L
A,T1,N1,M
A,T1,N1,T2
A,T1,N1,T3
A,T1,N2,J

Figure Appendix E-7 Applied Part Displacement.

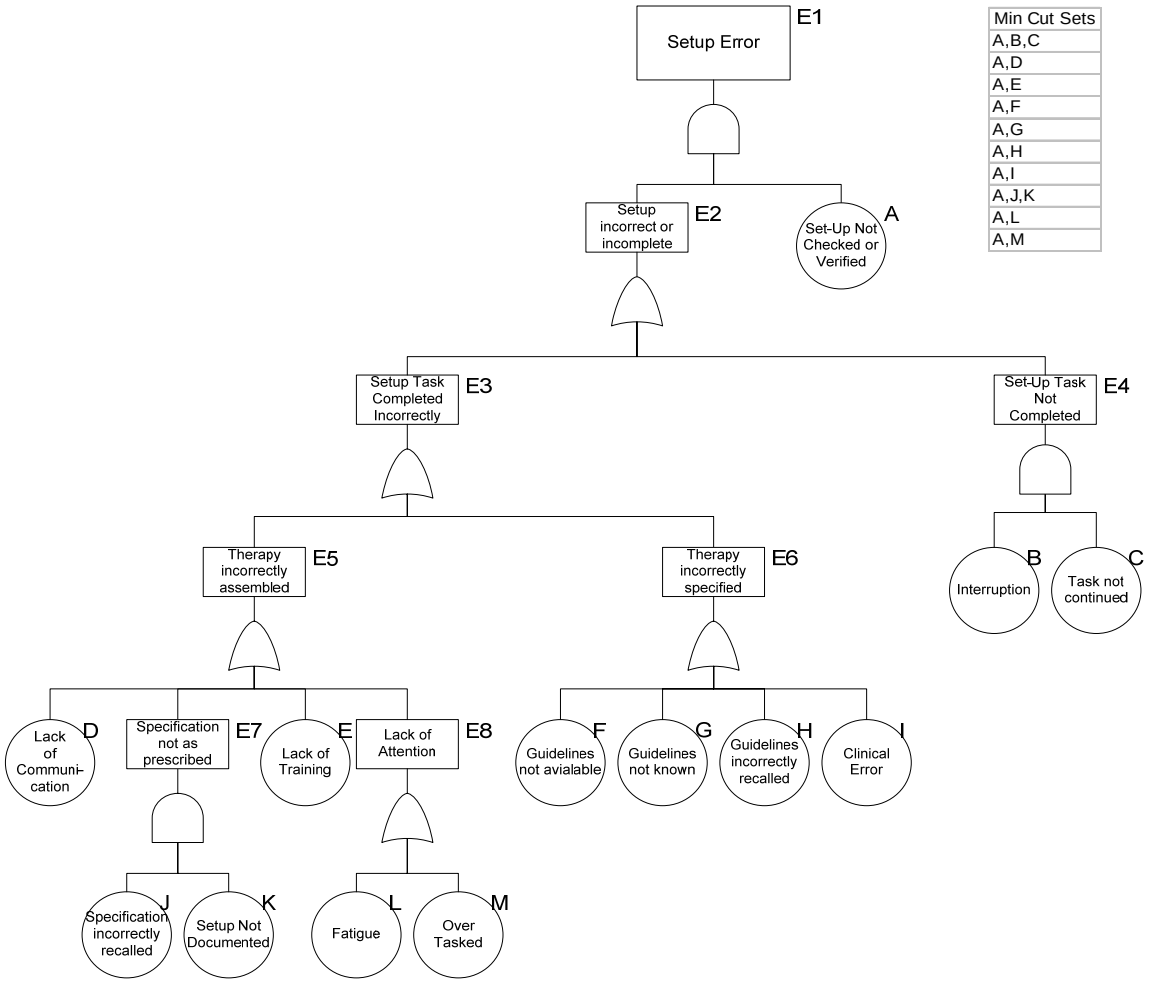


Figure Appendix E-8 Setup Error.

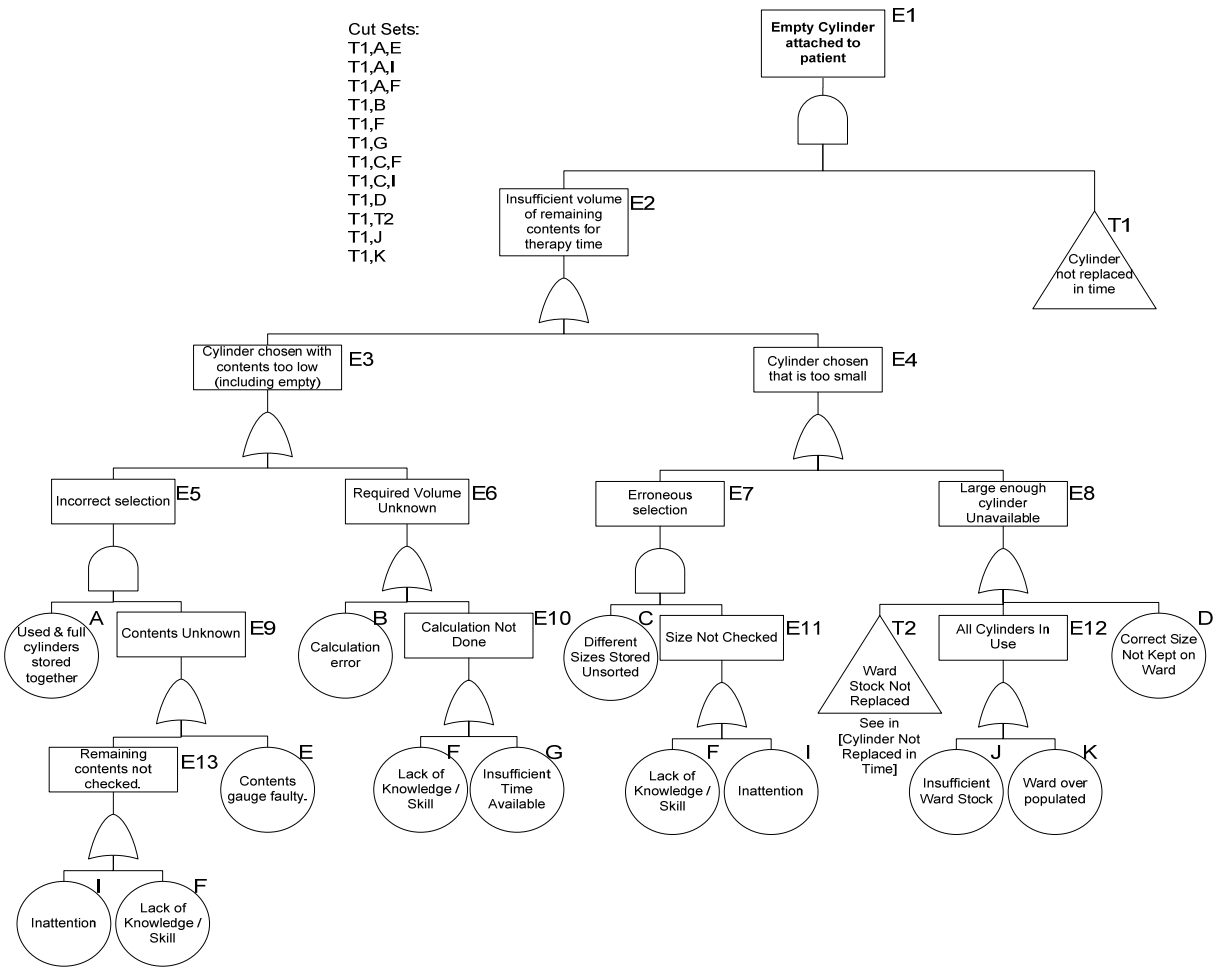
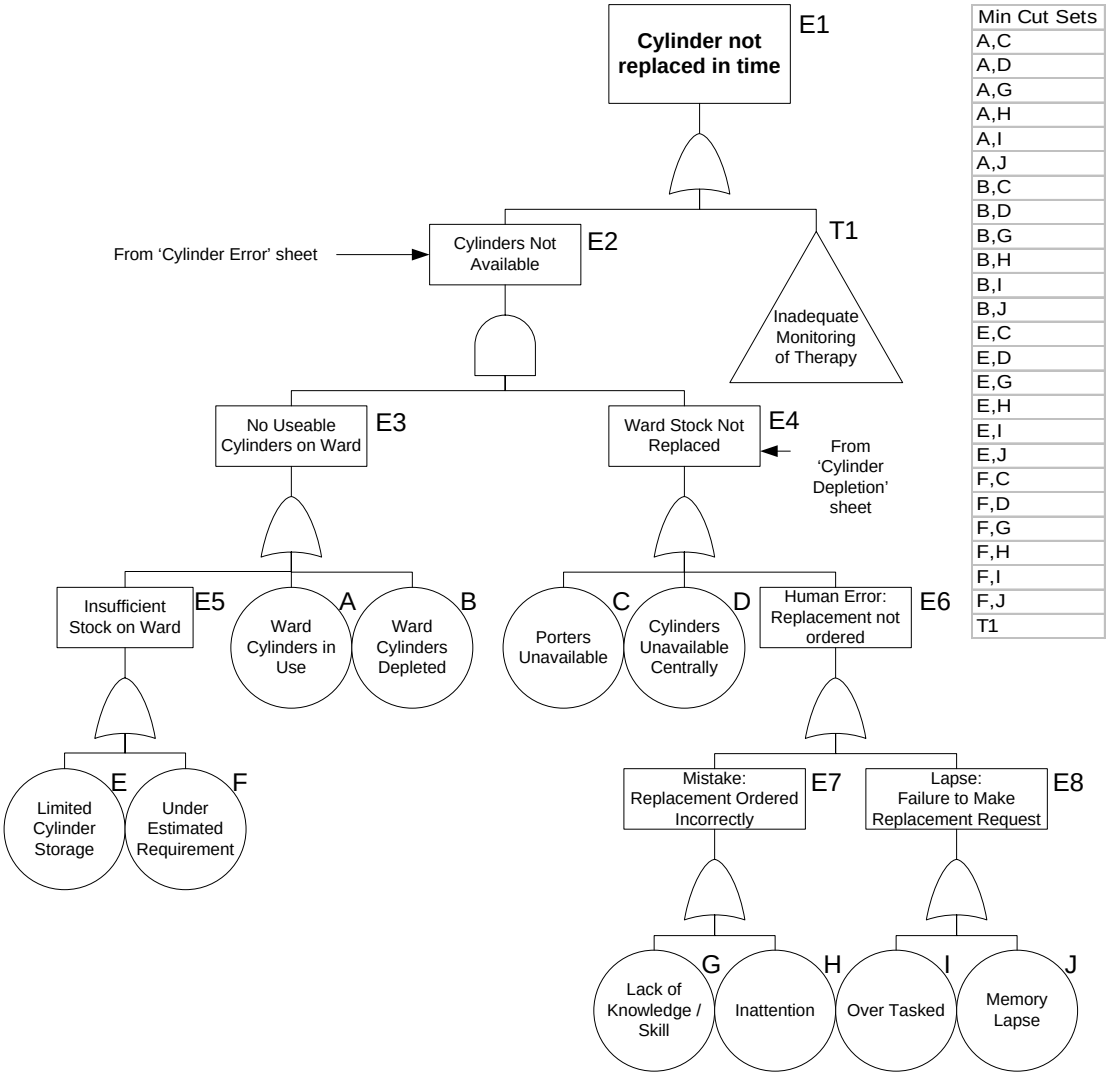


Figure Appendix E-9 Cylinder Attached to Patient.



Min Cut Sets
A,C
A,D
A,G
A,H
A,I
A,J
B,C
B,D
B,G
B,H
B,I
B,J
E,C
E,D
E,G
E,H
E,I
E,J
F,C
F,D
F,G
F,H
F,I
F,J
T1

Figure Appendix E-10 Not Replaced in Time.

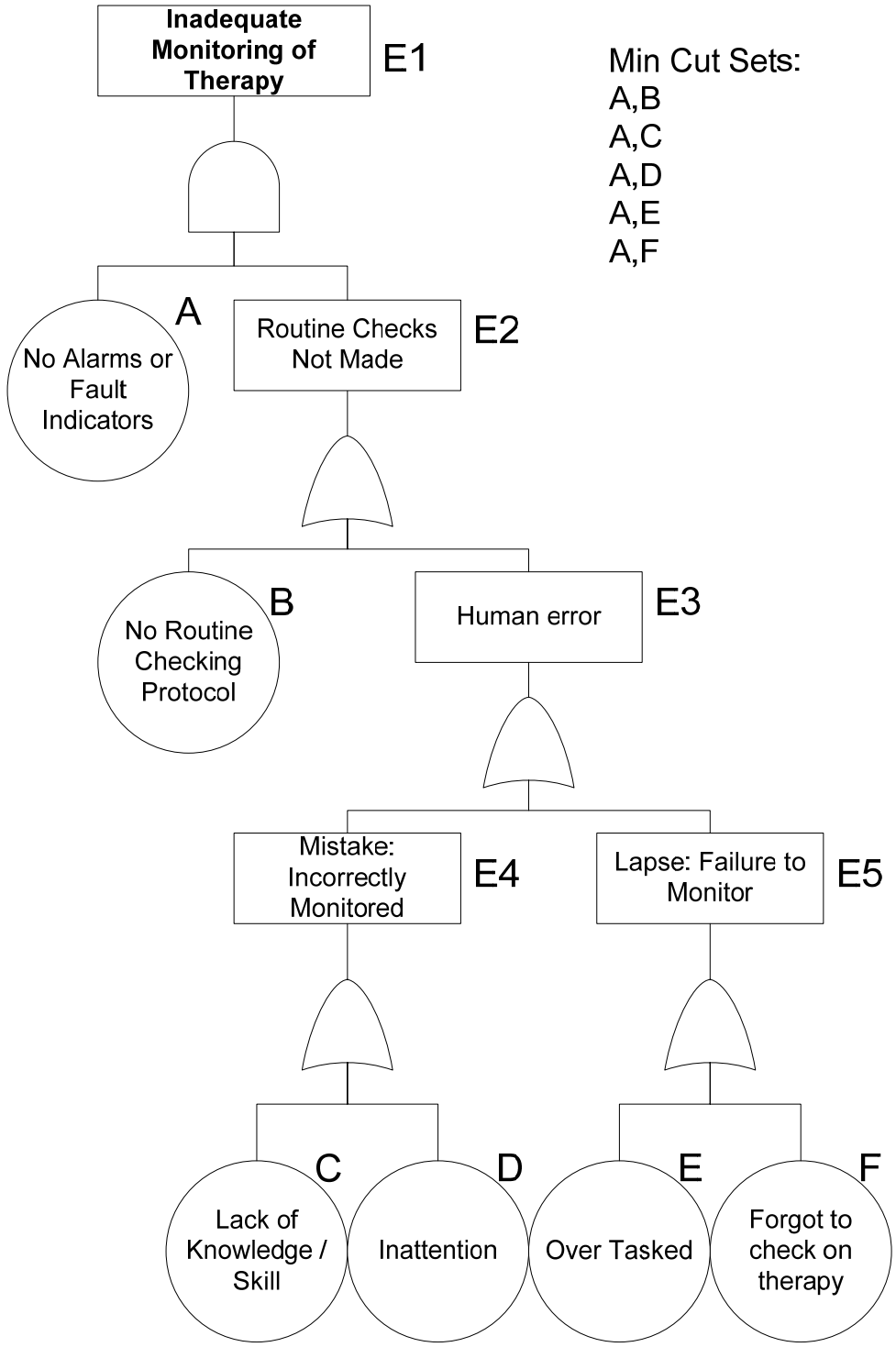


Figure Appendix E-11 Inadequate Monitoring of Therapy.

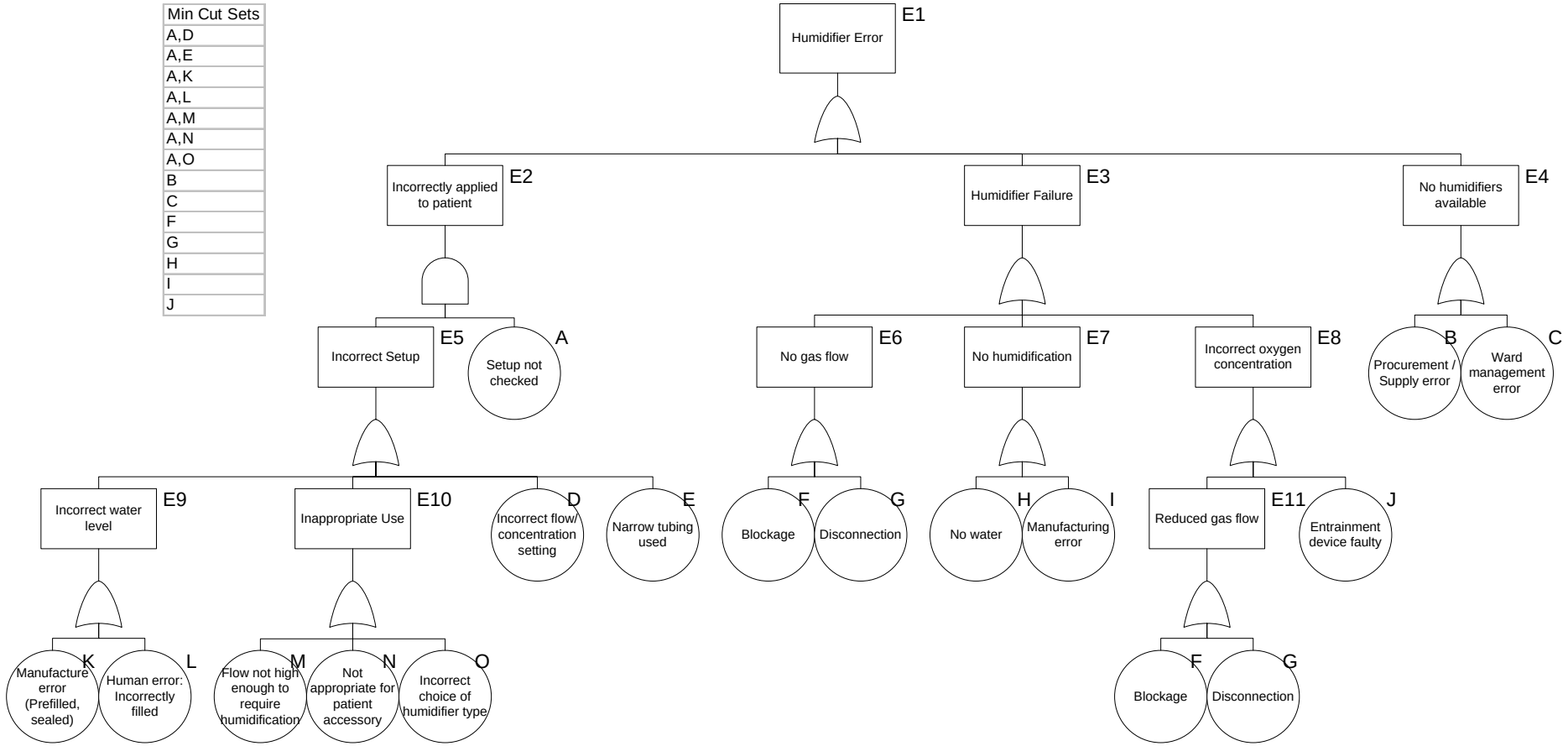
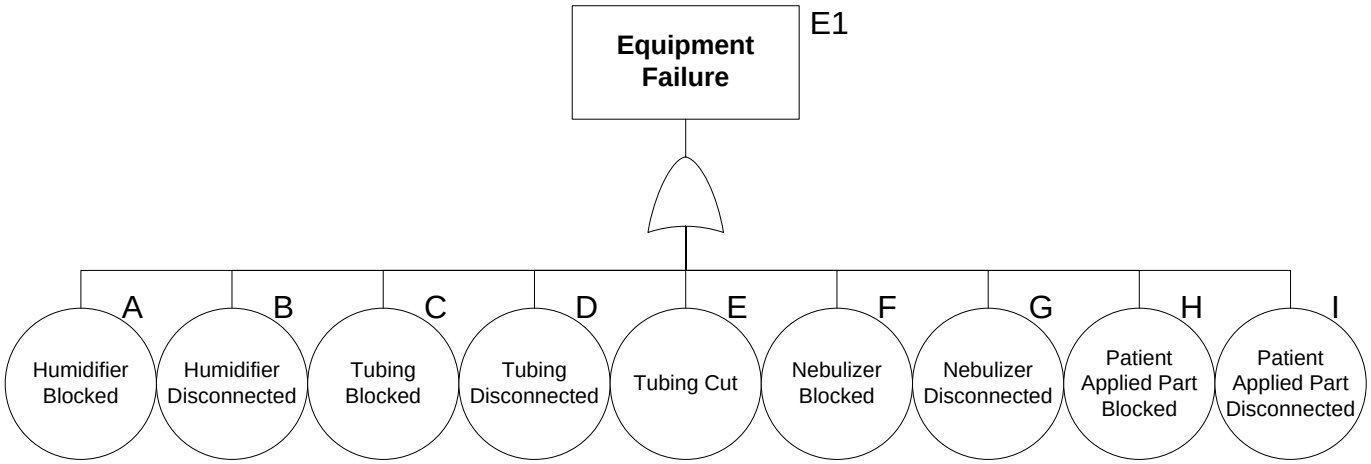


Figure Appendix E-12 Humidifier Error.



Cut Sets
A
B
C
D
E
F
G
H
I

Figure Appendix E-13 Equipment Failure.

E.3 Hazard and Operability Analysis

Table Appendix E.3-1 HAZOP of 15 January 2008.

Entity	Attribute	Guideword	Deviation from intent	Consequences	Likelhd (1 – 6)	Sevrty (1 – 6)	Safegrds (Y / N)	Actns (Y / N)	Risk	Notes
1. Piped Oxygen Supply	1. Gas Type	As Well As	1. Correct gas mixed with another substance	Harm to one patient	1	5	y	y	5	
				Harm to multiple patients	1	6	y	y	6	
		Part Of	2. Correct gas for some of the time, changing to wrong gas.	Harm to one patient	1	5	y		5	
				Harm to many patients	1	6	y		6	
		Other Than	3. Wrong Gas	Hypoxic gas like helium would cause miltiple harm	1	6	y		6	
	2. Pressure / Supply	No	1. No pressure	Single outlet, single patient no therapy(Would require there to be no cylinders available simultaneously)	1	5	y		5	
				Single outlet, single patient reguiring cylinder.	1	2	y		2	
				Multiple outlets, insuficient cylinders	1	6	y		6	
				Multiple outlets, Multiplr patients requiring cylinders	1	2			2	
		More	2. Too much pressure	Higher than set flow rate	1	2			2	
				Equipment damage, harm to multiple patients	1	6			6	
		Less	3. Not enough pressure	Muliple patients affected. Possible lower than required therapy	2	3			6	
		Part Of	4. No gas for some time and then gas supply reinstated	Fluctuating supply; difficult to detect	2	3			6	
	3. Availability of Ports	No	1. No ports available	If detected: Patient placed on less reliable cylinder supply	6	1	y	y	6	
				If detected: Patient moved to another ward	4	2	y		8	

Entity	Attribute	Guideword	Deviation from intent	Consequences	Likelhd (1 – 6)	Sevrty (1 – 6)	Safegrds (Y / N)	Actns (Y / N)	Risk	Notes
				(Gender specific bays or no cylinders available)						
				If undetected: Similar to no pressure, but more hazardous due to unawareness	6	5	n	y	30	
				Move patients around within the ward giving priority to those with high flow rate requirement	6	1	n	y	6	
		More	2. More than one port in close proximity	Patient connected to a port that is not turned on	2	2	n	y	4	
				Patient plugged into outlet of wrong gas	2	5			10	
				Wrong flow meter adjusted giving two patients wrong therapy	2	4			8	
				Many patients on medium to high flow rates causing a drop in supply pressure to that area.	1	6			6	
		As well as	4. Gasses of different types in close proximity	Harm to one patient possible in Critical care areas.	1	3			3	This cannot happen on general wards as there is only one gas outlet. On critical care, patients are carefully monitored, so consequences would be detected and mitigated
2. Cylinder Oxygen Supply	1. Contents	No	1. No gas	No therapy, possible death	5	5	y	y	25	
				Delay while cylinder is replaced	5	1			5	
		Less	3. Too little gas (failure in use)	No therapy, possible death	5	5	y	y	25	
		As well as	4. Correct gas mixed	Contaminated supply,	1	5	n	n	5	

Entity	Attribute	Guideword	Deviation from intent	Consequences	Likelhd (1 – 6)	Sevrty (1 – 6)	Safegrds (Y / N)	Actns (Y / N)	Risk	Notes
			with another substance	patient poisoned						
				Substance in cylinder valve causes regulator to fail	1	5	y	n	5	
		Other than	7. Wrong gas	Severe harm or death if undetected. Possibility of the same cylinder being used again.	1	5	n	y	5	
	2. Availability of Cylinders	No	1. No cylinders available	No Therapy.	1	5	y	y	5	
				Delay while cylinder is replaced	4	3	y	y	12	
		More	2. Too many cylinders available	Problems with storage and physical hazards from manual handling.	1	2	y	n	2	
		Less	4. Too few cylinders available	Posibility of running out. Most serious patients will be on wall supply. Possibility of problems for transfers.	2	6	?	y	12	
		As well as	5. Cylinders of different gas types stored together	Possibility of taking cylinder of wrong gas	?	?	?	y		
			6. Empty, part used and full cylinders in same storeage area	Difficult to manage stock and possibility of delays or therapy failures.	6	5	n	y	30	
		Other than	7. Only cylinders of different gas types available	No therapy	1	5			5	
		Late	8. Cylinder made available too late	Delayed therapy	2	5	?	n	10	Stock control issue
	3. Position / Placement	As well as	1. Cylinder or trolley protruding into next bed space	Physical hazard.	6	2			12	
				Tubing not able to reach patient	6	2			12	
		Other than	2. Cylinder in another	Physical hazard.	2	2			4	

Entity	Attribute	Guideword	Deviation from intent	Consequences	Likelhd (1 – 6)	Sevrty (1 – 6)	Safegrds (Y / N)	Actns (Y / N)	Risk	Notes
			bay/bed space	Tubing not able to reach patient	2	2			4	
		Below	4. Cylinder too low	Tubing not able to reach patient	5	1	n	y	5	
		Behind	5. Cylinder obscured or obstructed	Physical hazard.	5	1	n	y	5	
				Problems moving the patient	6	2	n	y	12	
		In front	6. Cylinder obscuring or obstructing something	Physical hazard.	6	2	n	?	12	
		Through	7. Cylinder being moved through an area	Collision hazard	2	2	?	?	4	
		Over	8. Cylinder placed on top of something	Physical hazard.	2	1	n	n	2	Cylinders are sometimes placed on beds
		Under	9. Something on top of cylinder	Cylinder becomes obstructed	2	1	n	n	2	linked hazard with 'Obscured cylinder'
	4. Properly secured	No	1. Not secured	Falling cylinder	6	2	n	y	12	
		Less	2. Inadequately secured	Falling cylinder	3	2	y	y	6	
		Part of	3. Secured but not according to proper procedure or regulations	Falling cylinder	5	2	?	y	10	
	5. Cylinder Type/ Size	Other Than	1. Cylinders do not fit into emergency trolleys	Cylinders have to be brought to an emergency seperately, causing delay	?	?	?	y		
			2. Cylinders do not have sufficient contents.	Possibility of undetected depletion.	?	?				
3. Pressure Regulation	3. Pressure Information	More	2. Pressure indicated as higher than true value (over reading)	Strong posibility of undetected depletion because pressure indicates more content than is the case	?	5	?	y		

Table Appendix E.3-2 HAZOP of 22 January 2008, Worksheet 1.

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards	Actions
							(Y / N)	**(Y / N)**
1. Patient	Age	Above	Over a certain age	No Hazard	Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
		Below	Below a certain age	Possibility of Retinopathy in premature babies	Catastrophic		y	Y:
					Major	1	Monitoring, Training, BGA, TCM	
					Moderate			
					Minor			
					Negligible			
	Condition	More	Condition worse than expected	1. Patients recovering from surgery on wards	Catastrophic	3	y	Y
				2. Any medical patient can get worse	Major	4	Mandatory	Minimal
					Moderate			
					Minor			
					Negligible			
		Less	Condition improves	Patient could get better and no longer require oxygen therapy	Minor	1	y	n
					Negligible			
		As Well As	Combined Conditions	1. Confusion due to dementure or mental health may result in patient removing therapy	Catastrophic	1	y	y
				2. Tracheostomies - Special equipment required	Major			

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards	Actions
				3. COPD; Retainer with M.I.	Moderate			
				4. Drug abuse	Minor			
				5. Unnoticed secondary condition (see also 1.2.1)	Negligible	5		
1. Patient	Condition	Other Than	Conditions that cannot be treated with plain Oxygen Therapy. (Not mechanically assisted)	See condition worse than expected	Catastrophic	3		
					Major	4		
					Moderate			
					Minor			
					Negligible			
	Actions	Other than	Patient takes action that interferes with oxygen therapy	See co-operation and combined conditions				
			Tampering	Patient fiddles with therapy due to	Catastrophic		y	y
				boredom, Attention seeking, percieved need	Major			
					Moderate			
					Minor	3		
					Negligible			
			Self harm	Suicide using oxygen tubing	Catastrophic	2	y	y
							Policies	Needs Review
							training	
	Co-operation	No	Patient will not co-operate with staff	Patient wants to die	Catastrophic			

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards	Actions
				Wants to do something off the ward	Major			
				Patient does not like the therapy	Moderate			
					Minor	2		
					Negligible	5		
		Part Of	Patient complies with part of instruction	May be result of negotiation	Catastrophic		y	y
				May result in sub optimal care	Major		Monitoring	Review
					Moderate		Assessment	
					Minor		Documentation	
					Negligible	1		

Table Appendix E.3-3 HAZOP of 22 January 2008, Worksheet 2.

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards (Y / N)	Actions (Y / N)
Patient / Clinical Staff Communication	Direction	Part Of	Communication is one way	1. Staff to patient. Patient cannot receive due to stroke or coma. No direct hazard except that problems cannot be made known and there is an 'increased likelihood of exacerbation of an issue	Catastrophic	1		
					Major			
				2. patient to staff only: May cause anxiety and frustration, but it is hard to identify a hazard	Moderate			
					Minor			
					Negligible			
	Clarity	No	No understanding achieved	Possible delay in actionfrom either party.	Catastrophic	1		
					Major			
					Moderate			
					Minor			
					Negligible	5		
		Part of	Some understanding is achieved	Patients need is communicated(e.g. they need a drink), but patient does not know what to do in order to consume the drink and so patient goes thirsty	Catastrophic			
					Major			
					Moderate	3		
					Minor			
					Negligible			
		Other Than	Misunderstanding	Posibility of treatnent errors because of false responces during an assessment. Especially with taking histories.	Catastrophic			
					Major			
					Moderate			
					Minor	1		
					Negligible			

Table Appendix E.3-4 HAZOP of 22 January 2008, Worksheet 3.

Entity	Attribute	Guideword	Interpretation	Possible deviations. (May include direct harm to the patient or a cascade of events which may lead to harm.)	Severity	Likelihood	Safeguards (Y / N)	Actions (Y / N)
3. Clinical Staff	Knowledge / Skill	No	No knowledge of oxygen therapy		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
		Part Of	Some Knowledge of oxygen therapy		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
	Availability	No	Staff not Available		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			
		Part Of	Staff Available for some of the time		Catastrophic			
					Major			
					Moderate			
					Minor			
					Negligible			

E.4 Hazard Analysis Methods Comparison

In Table Appendix E.4-1' below, the following symbols and colour codes are used:

✓	Indicates that a hazard has been fully identified
~	Indicates that a hazard has been only partly identified
X	Indicates that a hazard has not been identified

Table Appendix E.4-1 The Comparison of Hazard Analysis Methods.

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
All	All	38	Technical or physical failures of the bed or associated equipment	Malfunctioning bed or associated equipment	Equipment failure	X	X	X	X	
All	All	5	Non clinical staff rectifying an environmental fault	Unexpected events due to non clinical maintenance work	Environmental control mechanism failure, Lack of vigilance	X	X	~	X	
All	External - Environment	185	Fire hazard - Faulty nearby electrical equipment	Fire in an oxygen enriched environment	Faulty electrical equipment at or near an oxygen enriched bed space	~	✓	✓	X	
All	External - Infrastructure	146	Lifts are shared with all building users	Extended and unpredictable transfer times	No dedicated lift Access for patient transfers	X	X	X	X	
All	External - Manufacturer	195	Non-Standard equipment fitting sizes	Non-Standard equipment fitting sizes	Manufacturing error, inappropriate modification	~	~	~	X	
All	External - Person	162	Actions of Paediatric Patient's Parents	Inappropriate actions by parents of paediatric patients	Poor communication and involvement with parents	X	X	X	X	
Clinical	External - Environment	52	Environmental factor obstructing access to the patient	Obstructed access to patient	Environmental factor	X	X	X	X	
Clinical	External - Environment	33	Surplus equipment cluttering the ward area	Obstructed access or confusion	Cluttered ward area	X	X	X	X	
Clinical	External - Environment	39	Interference from an environmental factor affecting a nurses actions in the use of equipment	Equipment use error	Interference from an environmental factor	X	✓	~	X	
Clinical	External - Environment	51	Environmental factor obscuring a clear view of the patient	Obscured view of patient	Environmental factor	X	X	X	X	
Clinical	External - Environment	27	Environmental factors such as noise masking calls for assistance	Unanswered calls for assistance	High levels of ambient noise	X	X	X	X	
Clinical	External - Environment	96	A factor relating to design within the therapy or the environment causes staff to be distracted	Distracted or inattentive staff	Human factors: Difficulty in administering therapy	X	X	✓	X	
Clinical	External - Infrastructure	190	Infrastructure - Emergency buzzer inaccessible	Emergency buzzer is out of reach or faulty	Poor room layout, equipment fault	X	X	X	X	
Clinical	External - Institutional	149	Lack of or poorly constructed guidelines	Poor guidelines	Assessing requirement or applying therapy	✓	✓	✓	X	
Clinical	External - Institutional	97	A latent error in a defined procedure causes mistakes	Latent error in a procedure	Incorrectly defined procedure	~	~	✓	X	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	External - Institutional	156	Excessive Work Load for Staff	Lack of staff or busy environment	Task overload, ward management failure, organizational failure	~	✓	✓	✓	
Clinical	External - Other Therapy	159	CPAP/BIPAP Problems	Incorrect oxygen concentration during CPAP or BIPAP	Setup error, oxygen supply failure, equipment failure/use error	X	X	X	X	
Clinical	External - Other Therapy	197	Other therapies - Unauthorized medications	Unauthorised medications	Patient administered or unprescribed medication	~	~	X	X	
Clinical	External - Person	214	Unauthorized administration of oxygen	Oxygen administered by unauthorized person or without clinical authorization	Human error, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	~	X	X	X	
Clinical	Patient	64	Equipment delivering another therapy fails causing interference with this one	Interference with the therapy	Equipment Failure for another therapy	X	X	X	X	
Clinical	Patient	68	Unintentional action by patient interferes with the therapy	Undetected therapy failure	Patients actions	✓	✓	✓	✓	
Clinical	Patient	70	Action taken by a patient related to natural relief compromises the therapy	Suspension of therapy	Patient leaves the bed to go to the toilet	✓	✓	✓	~	
Clinical	Patient	71	Action taken by a patient to relieve discomfort compromises the therapy	Suspension of therapy	Patient changes position or moves between bed and chair	✓	✓	✓	~	
Clinical	Patient	73	Patient has to take action to enable them to talk, eat or drink	Suspension of therapy or food/drink not consumed	Patient has to suspend the therapy to enable them to talk, eat or drink	✓	✓	✓	X	
Clinical	Patient	73.1	Patient has to take action to enable them to take oral meds	Suspension of therapy or oral meds not taken	Patient has to suspend the therapy to enable them to take oral meds	✓	~	~	X	
Clinical	Patient	74	Actions by patient causes them to become entangled in the oxygen tubing	Patient entanglement	Patient movements	✓	~	X	X	Incomplete FTA and HAZOP is most likely cause for not identified. FMEA only mentions entanglement with relation to tubing being too long.
Clinical	Patient	77	Movements or actions during sleep compromise the therapy	Undetected therapy failure	Unintentional patient actions or movements	✓	~	✓	X	
Clinical	Patient	80	Innocent action by patient compromises the therapy	Undetected therapy failure	Unintentional	~	~	✓	X	
Clinical	Patient	91	The patients condition minimises communication and involvement	Limited information, patient involvement and feedback	Lack of communication	X	~	X	✓	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Patient	66	A patient takes action related to another therapy, which compromises this one	Undetected therapy failure	Patients actions related to another therapy	~	~	X	~	
Clinical	Patient	93	Patient vomiting while an accessory is in position	Vomiting into a face mask	Lack of vigilance, ineffective patient monitoring	X	~	~	~	Patient Error fault tree not complete
Clinical	Patient	153	Smoking	Fire	Smoking in an oxygen rich environment	X	X	X	X	
Clinical	Patient	82	Patient refuses to co-operate with the therapy by removing an accessory and ignoring requests to replace it	Misplaced accessory	Patient co-operation	✓	✓	✓	✓	
Clinical	Patient	69	Unauthorized or inappropriate action by the patient	Undetected therapy failure	Unauthorized or inappropriate action by the patient	~	✓	✓	✓	
Clinical	Patient	22	Impaired speech due to the face mask or other aspect of the therapy making communication difficult	Lack of communication through impaired speech	A face mask or other aspect of the therapy causing impairment	X	X	X	~	
Clinical	Patient Monitoring	92	Undetected change in patient condition	Undetected change in patient condition	Lack of vigilance, ineffective patient monitoring, interference from an environmental factor	~	✓	~	✓	Patient Error fault tree not complete
Clinical	Patient Monitoring	127	Failure to adequately monitor a patient during treatment with another therapy	Undetected change in patient condition	Lack of vigilance	X	✓	X	✓	This seems like a missed duplicate
Clinical	Patient Monitoring	194	Monitoring equipment - Physical harm from sensors	Sensors left in the same position for too long	Human error, lack of knowledge/skill	X	X	X	X	
Clinical	Patient Monitoring	201	Patient monitoring - Equipment unavailable	No patient monitoring equipment available	Equipment management error, Patient management error	~	✓	X	X	Incomplete FTA and HAZOP
Clinical	Patient Monitoring	44	Undetected disconnection of patient monitoring equipment	Undetected monitoring failure	Monitoring equipment disconnection	X	~	X	X	Incomplete FTA and HAZOP
Clinical	Patient Monitoring	141	Sensitive alarms and persistent nurse calls from patients	Undetected therapy failure	Frequently occurring alarms	X	X	X	X	
Clinical	Patient/External - Person	188	Inappropriate advice to patient from unauthorized person	Incorrect or inappropriate advice	Untrained staff, visitors giving advice	X	X	X	X	
Clinical	Patient/Patient Monitoring	47	Patient actions adversely affecting patient monitoring	Interference with patient monitoring	Patients actions	X	X	X	X	
Clinical	Patient/Staff	72	Patient refuses to co-operate with clinical staff regarding the therapy	Suspension of therapy	Lack of patient co-operation	✓	✓	X	✓	Incomplete FTA

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Patient/Therapeutic Subsystem	206	Self Harm - Strangulation with oxygen tubing	Self Harm - Strangulation with oxygen tubing	Patient not assessed as "At-risk", Lack of vigilance	X	X	X	✓	
Clinical	Staff	175	Deviations from accepted procedure	Inappropriate deviation from accepted procedure	human error, lack of knowledge/skill, insufficient process checks	~	~	~	X	Incomplete HAZOP
Clinical	Staff	14	Administering or adjusting another therapy causes interference with this one	Interference from adjustment of another therapy	Human error, lack of knowledge/skill, Lack of vigilance	✓	X	X	X	Why?
Clinical	Staff	65	A required action related to another therapy causes a distraction which compromises this therapy	Staff distraction	Action required for the administration of another therapy	✓	~	~	X	Incomplete HAZOP
Clinical	Staff	9	Inadequacy of pro forma or another communication tool	Information missing or incorrect	An inadequate communication tool	~	~	~	X	Incomplete HAZOP
Clinical	Staff	20	Calls for assistance unanswered	Unanswered calls for assistance	Lack of vigilance	X	X	X	~	See 'one way communication'
Clinical	Staff	100	Insufficient staff numbers to effectively manage patients receiving therapy	Lack of staff	Management error, Institutional issue	✓	~	~	~	Incomplete FTA and HAZOP
Clinical	Staff	109	Incorrect action taken when attempting to rectify a setup error	Incorrect action	Setup error and human error	~	~	~	~	
Clinical	Staff	18	Process or patient management errors moving patients from one bed to another	Patient placed in an inadequate bed space	Moving patients between bed spaces	~	X	X	X	
Clinical	Staff	128	Patient requirement incorrectly assessed	clinical error: diagnosis/assessment	Human error, Lack of Knowledge / Skill	~	✓	✓	X	
Clinical	Staff	13	Clinical activity interfering with the therapy	Unexpected influence on therapy by routine tasks.	Interference from clinical interventions to patient receiving oxygen therapy	✓	X	X	X	Why?
Clinical	Staff	167	Communication/Structure - refusal to assess patient	Clinician cannot or will not assess patient	Institutional communication or structure errors	X	X	X	X	
Clinical	Staff	7	Latent error causes a failure in communication or process	Latent error in communication or process methods	Human error - mistakes in process definitions	~	~	~	~	
Clinical	Staff	164	Bed spaces not prepared	Bed spaces not adequately prepared for patients requiring therapy	Lack of staff, Task overload, ward management failure, organizational failure	~	X	X	X	
Clinical	Staff	6	Distraction caused by activity on the ward	Distraction of clinical staff	Unusual or intrusive activity on the ward	X	X	~	X	Possible missed duplicate?

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Staff	4	An environmental factor promotes inappropriate action	Inappropriate or incorrect action - Staff	Human factors - An environment of excessive Noise, Light, Darkness or discomfort	X	~	X	X	Incomplete FTA and HAZOP
Clinical	Staff	143	Staff are allowed to undertake tasks without adequate or relevant skills or knowledge	No method available to prevent unauthorized staff attempting clinical or nursing tasks	Lack of skill/knowledge, protocol / procedure error	✓	✓	✓	✓	
Clinical	Staff	1	Incorrect clinical decision or action	Clinical Error - Undetected incorrect clinical decision or action	Incorrect information, lack of knowledge or skill, human error	✓	✓	✓	X	Incomplete HAZOP
Clinical	Staff	8	Patient management errors when patients arrive after transfer	Patient placed in an incorrect ward or bed space.	Patient Management error	X	X	X	X	A 'Forgotten hazard'?
Clinical	Staff	24	Missing or incomplete patient notes	Missing or incomplete patient notes	Human error - Notes mislaid or misfiled	~	✓	~	X	
Clinical	Staff	61	Failure to act on a detected therapy administration error	Failure to act on a Therapy administration error	Human error	~	X	X	X	This is surprising
Clinical	Staff	41	Failure of staff to communicate regarding equipment required in patient transfer	Unavailable equipment	Failure to communicate a requirement	~	~	~	X	See Top Level Fault Tree (combined system and task), bottom event 'C'
Clinical	Staff	30	Prescriptions or treatment orders incorrect or not made	Incorrect action	Communication, protocol or procedure failure	✓	✓	✓	X	Incomplete HAZOP
Clinical	Staff	29	Nursing staff not responding to requests or orders from doctors	Failure to act	Communication or protocol failure	~	~	~	X	Incomplete HAZOP
Clinical	Staff	211	Transferring without adequate escort	Patients on oxygen therapy transferred without escort	Human error, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	X	X	X	X	A 'Forgotten hazard'?
Clinical	Staff	46	Failure to respond to patient or therapy monitoring alerts due to a lack of staff	No response to monitoring alerts	lack of staff	✓	~	~	X	
Clinical	Staff	21	Patient requests or needs unfulfilled	Unfulfilled patient need	Failure to act	X	X	X	X	This is something of a general issue
Clinical	Staff	63	Failure to act on a detected early therapy termination	Failure to act on an early therapy termination	Human error	X	X	~	X	
Clinical	Staff	23	Communication failures at patient hand-over	Poor communication at patient handover	Poorly defined process, not following procedure, complacency	✓	~	~	X	
Clinical	Staff	26	Poor communication between doctors and nursing staff regarding setup or adjustment	Incorrect action or no action	Communication failure between clinical staff	~	✓	✓	X	Incomplete HAZOP

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Staff	59	Incorrect actions at patient handover	Protocol/procedure error: Incorrect action	Handing over care from one team to another	X	X	X	X	Indirect hazard
Clinical	Staff	25	Incorrect information in patient notes	Incorrect information entered into patient notes	Human error - Mistakes when writing notes, wrong patients notes written in	~	~	X	X	
Clinical	Staff/Cylinder	155	Delays or failures with Cylinder Replacement/Refilling	Lack of available cylinders	Request for replacement not made, request not received or handled by porters, insufficient central stock	✓	✓	✓	✓	
Clinical	Staff/Cylinder	161	Cylinder Identification	Staff unable to identify cylinder contents	Staff knowledge, improper/ unclear or missing content label/colour code	~	~	✓	~	
Clinical	Staff/Cylinder	216	Use Error - Cylinder not switched on	Cylinder not turned on at setup	Human error, lack of knowledge/skill, Communication error	X	✓	X	X	
Clinical	Staff/Cylinder	209	Staff knowledge/Skill - not able to identify an oxygen failure alarm	Staff unable to identify oxygen cylinders	Unmarked/labelled/coded cylinders, lack of knowledge/skill	X	X	X	X	A 'hidden hazard'?
Clinical	Staff/Cylinder	173	Cylinder management error - Not turned off after use	Cylinders placed in storage without being turned off	Human error	X	X	X	X	A 'hidden hazard'?
Clinical	Staff/External - institutional	210	staff unavailable - too busy	Staff unavailable	Lack of staff, Task overload, ward management failure, organizational failure	~	~	~	~	
Clinical	Staff/External - Person	203	Procedural error - Delegating clinical/nursing tasks to parents	Clinical tasks inappropriately delegated to parents	lack of knowledge/skill, Human error, procedure/protocol error, lack of staff	X	X	X	X	A 'hidden hazard'?
Clinical	Staff/Patient	58	Incorrect action when responding to a change in a patients condition	Clinical error: incorrect action	Change in patients condition	X	~	X	X	
Clinical	Staff/Patient	134	Other medication interfering with this therapy	Undetected drug interference	Communication error, Human error, Lack of Knowledge / Skill	✓	X	X	X	Why wasn't this transferred to either the FMEA or the FTA?
Clinical	Staff/Patient	55	Changing a patients posture or position interferes with the therapy	Interference with the therapy	Change in patients posture or position	X	X	X	X	A 'Forgotten hazard'?
Clinical	Staff/Patient	28	Communication failures between clinician and patient during an examination	Incorrect or incomplete information or diagnosis	Misunderstanding between doctor and patient	X	~	~	✓	Could be said to be part of 'Clinical Error'
Clinical	Staff/Patient	56	Preparing a patient for transfer interferes with the therapy	Interference with the therapy	Preparation for transfer	✓	X	X	X	Another serious omission?

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Staff/Patient	57	Moving a patient between bed and chair causes interference with the therapy	Interference with the therapy	Transferring a patient between bed and chair	X	X	X	X	A 'Forgotten hazard'?
Clinical	Staff/Patient	139	Confusion with therapies common to two patients in close proximity	Bed spaces are in close proximity	Proximity of bed spaces, Poor ward layout, Patient management error, Ward management error, Central bed management error	X	X	X	✓	A 'Forgotten hazard' identified by HAZOP?
Clinical	Staff/Patient	49	Failure to detect patient entanglement in oxygen tubing	Undetected patient entanglement	Lack of vigilance	✓	~	X	~	
Clinical	Staff/Patient	200	Patient left unattended	Unattended patient on an oxygen cylinder	Human error, Organizational error, Process/protocol error	X	X	X	X	A 'forgotten hazard'?
Clinical	Staff/Patient	158	Retrolental Fibroplasia	Oxygen overdose to neonate	Human error, Clinical error	~	X	X	✓	
Clinical	Staff/Patient	165	Clinical Error - Making decisions without reference to diagnostic results	Decisions made without reference to diagnostic results	Urgency, human error, delayed results	~	~	~	~	
Clinical	Staff/Patient	205	Procedural delay - Examination	Delay in conducting an examination	Human error, lack of staff, Task overload, ward management failure, organizational failure	~	X	X	X	
Clinical	Staff/Patient	148	Incorrect management of patients with COPD	COPD	Incorrect therapy or wrong dose	✓	~	~	✓	
Clinical	Staff/Patient Monitoring	45	Failure to respond to or implement patient monitoring	Undetected therapy failure	Patient monitoring error through failure to act	✓	✓	✓	X	
Clinical	Staff/Patient Monitoring	35	Mistakes or equipment failures when changing from portable to installed monitoring or vice-versa	Ineffective patient monitoring	Human error or equipment failure when changing between monitoring devices	✓	X	X	X	
Clinical	Staff/Patient Monitoring	43	Human error by clinical staff when monitoring patients	Undetected therapy failure	Lack of vigilance through patient monitoring error	~	~	~	X	
Clinical	Staff/Therapeutic Subsystem	215	Unsuitable running repairs	Inappropriate running repairs done to therapy system	Equipment fault, Lack of available replacements, procedure/process error, lack of knowledge/skill	X	X	X	X	An indirect hazard
Clinical	Staff/Therapeutic Subsystem	192	Interference from nursing tasks - Accidental therapy disconnection	Accidental disconnection at any point in the therapy system	Human error, loose connections	~	~	~	X	
Clinical	Staff/Therapy Monitoring	131	Incorrect action when responding to or implementing patient monitoring	Incorrect action	Human error, Lack of Knowledge / Skill	~	~	~	X	
Clinical	Staff/Therapy Setup	191	Insufficient cylinder contents for transfer	Insufficient cylinder contents for transfer	Contents not checked before transfer, replacement cylinder not ordered in time	~	X	X	~	

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Staff/Therapy Setup	176	Distraction of staff - Issue with this therapy puts other patients at risk	Staff are distracted by dealing with a problem with oxygen therapy	Human error, lack of staff, Task overload, ward management failure, organizational failure	X	X	X	X	A 'forgoten hazard'?
Clinical	Staff/Therapy Setup	169	Contamination hazard - Used accessories not disposed of and replaced	Accessories used by a previous patient left at the bed space	Human error, lack of staff, Task overload, ward management failure, organizational failure	X	X	X	X	A 'forgoten hazard'?
Clinical	Staff/Therapy Setup	136	Therapy not set up according to prescription or treatment order	Undetected setup error	Communication error, Human error, Lack of Knowledge / Skill	✓	✓	✓	X	
Clinical	Staff/Therapy Setup	154	Delayed Action from Staff	Delay in specifying, applying or adjusting therapy	Lack of staff or busy environment	X	X	X	X	
Clinical	Staff/Therapy Setup	183	Equipment not checked	Equipment placed into storage for re-use or taken for use without being checked	Human error, lack of staff, Task overload, ward management failure, organizational failure	X	X	X	X	A 'forgoten hazard'?
Clinical	Therapy Monitoring	40	Failure to respond to an equipment alarm or warning	Undetected therapy failure	Lack of vigilance through unattended alarms or equipment notifications	X	X	X	X	A 'forgoten hazard'?
Clinical	Therapy Monitoring	48	Failure of therapy monitoring to detect a therapy disconnection	Undetected therapy disconnection	Ineffective patient monitoring	X	X	~	X	A 'forgoten hazard'?
Clinical	Therapy Monitoring	50	Failure to detect cylinder depletion when in use	Undetected cylinder depletion	Lack of vigilance or information	✓	✓	✓	✓	
Clinical	Therapy Monitoring	62	Failure to detect that the therapy has terminated early	Undetected therapy termination	Therapy monitoring	~	~	~	X	
Clinical	Therapy Monitoring	54	Failure to notice an incorrectly positioned accessory	Misplaced accessory	Lack of vigilance	~	~	~	X	
Clinical	Therapy Monitoring	120	Failure by clinical staff to notice a patient disconnection	Undetected therapy disconnection	Lack of vigilance	~	~	~	X	
Clinical	Therapy Monitoring	129	Failure to respond to or implement therapy monitoring	Undetected therapy failure	Human error, Lack of Knowledge / Skill	~	✓	✓	X	
Clinical	Therapy Monitoring	2	Failure to recognize and act on an imminent therapy failure	Therapy failure (Undetected)	Lack of vigilance, knowledge or Skill	~	✓	✓	X	Incomplete HAZOP
Clinical	Therapy Setup	15	Wrong type of accessory used for a particular therapy setup	Wrong accessory for purpose	Human error, lack of knowledge/skill, Correct accessory not available	✓	✓	~	X	Incomplete HAZOP
Clinical	Therapy Setup	36	Equipment improperly checked	Unreliable equipment	Human error: Equipment checks	X	X	X	X	
Clinical	Therapy Setup	60	Incorrect actions during patient transfer	Protocol/procedure error: Incorrect action	Transferring a patient between wards/departments	X	X	X	X	FMEA very focussed on system components and none are linked to a specific context

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Therapy Setup	53	Accessory incorrectly administered or moved into an incorrect position by clinical staff	Misplaced accessory	Staff actions	~	✓	✓	X	
Clinical	Therapy Setup	113	A change of accessory is incorrectly implemented	Undetected setup error	Human error	~	~	~	X	Incomplete HAZOP
Clinical	Therapy Setup	126	Wrong type of accessory used for a particular therapy setup	Use error	Lack of Knowledge or Skill					Excluded: Duplicated hazard (see 15)
Clinical	Therapy Setup	123	Therapy incorrectly or inappropriately set up when re-administered after a previous termination	Undetected incorrect or inappropriate therapy re-administration	Re-administering the therapy after a previous termination	~	~	~	X	Incomplete HAZOP
Clinical	Therapy Setup	122	Flow rate incorrectly or inappropriately adjusted	Dosage error	Human error, Lack of Knowledge / Skill	X	~	✓	X	
Clinical	Therapy Setup	121	Failure to detect a setup error	Undetected setup error	Lack of vigilance	X	X	✓	X	
Clinical	Therapy Setup	119	Change either way between piped supply and cylinder incorrectly implemented	Undetected setup error	Human error	X	X	~	X	Task and context not well assessed
Clinical	Therapy Setup	207	Setup - Oxygen not turned on	Oxygen supply not turned on at setup	Human error, lack of knowledge/skill, Communication error	X	✓	X	X	
Clinical	Therapy Setup	117	An incorrect adjustment is made to the therapy	Undetected setup error	Human error	~	✓	✓	X	Incomplete HAZOP
Clinical	Therapy Setup	107	Mistakes in setting up the therapy	Undetected setup error	Human error	~	✓	✓	X	Related to 117
Clinical	Therapy Setup	105	A factor relating to design within the therapy or the environment causes setup error	Undetected setup error	Human factors: Difficulty in administering therapy	X	X	X	X	
Clinical	Therapy Setup	202	Pressure/Abrasion sores from accessories	Poorly fitting accessories left in place too long	Human error, setup error, Therapy management error	X	~	~	X	FMEA mentions discomfort but not harm. FTA Not complete. HAZOP not complete.
Clinical	Therapy Setup	137	A human factors issue with any equipment causes a functional failure because Equipment is applied differently to its intended use	Incorrect application of equipment	Equipment use error	✓	✓	✓	✓	FMEA: 1.4.1, 1.4.3 FTA: Applied Part Disconnected. HAZOP: 1.3.2, 1.3.4
Clinical	Therapy Setup	208	Setup error - Venturi mask	Flow rate does not match venturi specification	Human error, lack of knowledge/skill	X	~	~	X	FTA: Setup Error. Applied part error not fully assessed. HAZOP incomplete. FMEA: Insufficient detail in single pass assessment.

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Clinical	Therapy Setup/Supply	212	Transport without oxygen	Patients who require oxygen therapy are transported/transferred without	Human error, lack of knowledge/skill, Lack of staff, Task overload, ward management failure, organizational failure, procedure/process error	X	~	~	X	FTA and FMEA: The general issue of therapy not applied would include this. Specific contexts were not assessed. HAZOP incomplete but would possibly have the same result.
Clinical	Therapy Setup/Supply	218	Wrong wall port - Suction instead of oxygen	Patient connected to suction port instead of oxygen	lack of knowledge/skill, Human error, procedure/protocol error	~	~	~	~	The general issue of the wrong wall port being used was assessed, but not suction in particular. (Highly unlikely).
Supply	All	108	Undetected failed oxygen supply	Undetected supply failure	Lack of vigilance and Wall port failure, flow meter fault, Pipeline and alarm system failure or cylinder depletion	✓	✓	✓	✓	
Supply	Cylinder	170	Cylinder damage - Incorrect positioning on trolley	Aluminium cylinder crushed or punctured by bed or trolley height adjustment	Cylinder incorrectly positioned	X	X	~	~	Unsafe cylinder position assessed, but not in detail.
Supply	Cylinder	179	Equipment missing - Cylinder	Cylinder not in expected position	human error, theft, lack of cylinders	~	~	~	~	Covered under the general issue of cylinders not available.
Supply	Cylinder	174	Cylinder Quality - New cylinder empty	Unused, sealed new cylinder is empty	Manufacturing error, leaking cylinder	X	~	~	~	Covered partly under the general issue of cylinders not available.
Supply	Cylinder	172	cylinder faulty - leaking	Leaking cylinder	Faulty valve, faulty regulator, cracked /punctured cylinder	~	✓	~	~	Partly covered under the general issue of cylinder depletion.
Supply	Cylinder	180	Equipment missing - Cylinder key	No cylinder key available to turn on gas supply	human error, theft, lack of cylinder keys	X	✓	X	X	
Supply	Cylinder	32.1	Position of cylinder at the bed side causes unknown cylinder contents	Unknown cylinder contents	Obscured view of cylinder	~	~	X	✓	FMEA not detailed enough to identify this. Also based mainly on system diagram and not enough on process flow chart.
Supply	Cylinder	32	Position of cylinder at the bed side causes Physical obstruction	Physical obstruction at the bed side	Badly positioned Cylinder	X	X	~	✓	FTA mentions unsafe position but not in detail.
Supply	Cylinder	171	Cylinder Faulty - Cannot turn on gas	Cylinder valve cannot be opened	Damaged nut or faulty valve	~	~	X	X	FMEA mentions cylinder valve shut.
Supply	Cylinder	152.1	Wrong cylinder used	Wrong gas	Human error when applying therapy, Different cylinders stored together	✓	✓	✓	✓	
Supply	Cylinder	32.2	Position of cylinders at the bed side causes patients movements to be restricted by tubing position	Patients movements restricted by tubing position	Cylinder too far from patient	X	X	~	~	Issue of unsafe cylinder position, but not this detailed.
Supply	Cylinder	151	Manual Handling - Cylinders	Heavy, awkward cylinders	Moving or lifting cylinders	~	~	~	~	Falling cylinders, but not general manual handling.
Supply	Cylinder	150	Cylinder management - Unsecured/Unrestrained	Unrestrained cylinders	Moving or bumping into the cylinder	~	✓	✓	✓	FMEA: 1.2.5 FTA: Cylinder Error, E7 HAZOP: 2.4.2

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Supply	Cylinder/External - Institutional	204	Procedural delay - Cylinder restocking	Delay in replacement of empty cylinders	Ward management error, procedure/process error, communication error, human error	✓	~	✓	✓	Lack of consideration of external influences in the FMEA.
Supply	External - Infrastructure	147	Not enough oxygen outlets for the number of patients requiring therapy	Unavailability of piped oxygen outlets	Insufficient number of oxygen outlets	✓	✓	✓	✓	
Supply	External - Infrastructure	145	No provision for the safe and organized storage of oxygen cylinders	The chaotic storage of used and full cylinders together	Inadequate Storage	X	X	✓	✓	HAZOP mentions this explicitly. It is becoming clear that the FMEA depends on the hazard ID listing while the FTA is less reliant on it
Supply	External - Infrastructure	140	Two or more patients sharing a wall port or cylinder	Confusion with therapies common to two patients in close proximity	Shared resources, Human error, Ward layout error, Patient management error	X	X	X	~	HAZOP mentions wall ports in close proximity.
Supply	External - institutional	217	Ward management - Empty and full cylinders stored together	Empty and full cylinders stored together	Ward management error, procedure/process error, communication error, human error					Excluded as too similar to 145
Supply	External - Maintenance	196	Oil used on oxygen outlet	Oil used on the oxygen outlet or regulator components	Lack of Knowledge or Skill, maintenance tasks carried out by untrained staff	~	X	✓	X	It is surprising that the FMEA did not pick this up. This emphasizes the need for hazard analyses to be iterative and not just one-off processes.
Supply	Flow Regulation	186	Flow meter not properly attached to wall port	Improperly attached flow meter falling or being expelled out of wall port	Human error, faulty valve	~	X	X	X	HAZOP incomplete as is the FTA. Not covered explicitly in the Delphi, so missed by the FMEA too.
Supply	Flow Regulation	157	Flow Meter Fault	Incorrect indication of flow rate	Mechanical fault	X	✓	✓	X	HAZOP incomplete
Supply	Flow Regulation	181	Equipment missing - Flow meter	Flow meter missing from wall outlet or cylinder	human error, theft, lack of flow meters	~	✓	✓	X	FMEA: 1.4.2; FTA: Flow Regulator error.
Supply	Piped	152	Wrong Gas port used	Wrong gas	Human error when applying therapy	✓	✓	✓	✓	FMEA: 1.1.4; FTA: (2 places), Pipeline Error & Setup Error,E5. HAZOP: 1.3.2
Supply	Piped	166	Collision between patient and pipeline outlet hardware	Patients colliding with therapy outlet hardware	Patient movements, posture/position changes, patient transfers	X	X	X	X	Some physical hazards were completely missed by all the methods on a first pass.
Supply	Piped	168	Contaminated pipeline	Contaminants in oxygen pipeline	Ingress at a puncture, particles or chemicals from maintenance tasks	✓	✓	✓	✓	HAZOP: 1.1.1; FMEA: 1.1.2; FTA: Piped Supply Error, E3.
Supply	Pressure Regulation	163	Regulator Faults	Faulty pressure reducing regulator on a cylinder	Mechanical fault	✓	✓	✓	~	FMEA: 1.3; FTA: Cylinder Regulator Error; HAZOP: 3. The HAZOP analysis of regulators was stopped because the opinion was that this hazard no longer existed at BH because they had changed to encapsulated cylinders, but they are still present in even these, so this was a faulty deduction.

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Supply	Pressure Regulation	182	Equipment missing - Regulator	Regulator missing from cylinder	human error, theft, lack of regulators, not swapped over on cylinder replacement	X	✓	✓	X	As above
Supply	Pressure Regulation	199	Oxygen Regulator Fire	Fire or explosion of oxygen regulator	Manufacturing error, Maintenance error, Oil/debris ingress	✓	✓	✓	X	FMEA: 1.3.1a, 1.4.1a;
Therapeutic	All	178	Equipment design issue	Confusing or difficult to use equipment	Design error or insufficient attention to human factors	X	~	~	X	FMEA: 1.3.2, 1.4.3, 2.2.5, 2.2.6; FTA: Human error is included in Setup Error and Humidifier Error.
Therapeutic	All	198	Oxygen flow impeded - Accessory blocked	Occluded accessory	Debris or deposits, Manufacturing error, setup error	✓	✓	✓	X	FMEA: 2.3.10; FTA: Humidifier Error
Therapeutic	External - Environment	42	Environmental issues like noise or cramped space cause visitors actions to interfere with the therapy	Interference/tampering with the therapy	Visitors actions when reacting to the environment	~	X	~	~	FMEA does not seem to have captured many external influences. The top level FTA based on both the task and system diagrams reflects this, but the one based purely on the system diagram does not. This is an example of the need for an inclusive assessment.
Therapeutic	External - Institutional	99	A lack of available equipment for therapy administration or monitoring	Lack of Equipment	Management error, Purchasing/stores error	✓	✓	✓	✓	FTA and FMEA: Multiple examples. HAZOP: Only went as far as supply equipment.
Therapeutic	External - Institutional, Humidifier	193	Lack of resources; sterile water for humidifiers	No sterile water available for humidifiers	Resource management error, Central stores stock error	X	~	~	X	FMEA (2.2.4) and FTA (Humidifier Error) mention low water level. FTA also mentions no water
Therapeutic	External - Person	3	Unauthorized or inappropriate action by others	Inappropriate or incorrect action - unauthorized person	Lack of vigilance, Visitor management failure, unrestricted access	✓	X	✓	~	FTA: Applied Part Displacement; HAZOP: 1.3.1.2. FMEA based too heavily on the system diagram. FTA includes tampering, but does not specify by whom.
Therapeutic	External - Person	10	Innocent action by visitor to aid patient comfort compromises this therapy	Incorrect action by an unauthorized person	Therapy parameters are changed by uninformed action by visitor when patient or equipment is moved	~	X	X	X	Too specific. Covered to some extent by tampering but no enough to warrant a partial score.
Therapeutic	Humidifier	187	Humidifier use error - Refilled with saline	Humidifier refilled with saline	Human error, lack of knowledge/skill	~	X	X	X	Water covered, but not refilling.
Therapeutic	Humidifier	98	Humidifier incorrectly set up, used inappropriately or not used when it should	Humidification error	Lack of procedure/protocol, Lack of knowledge/skill, Human factors, Lack of equipment	✓	✓	✓	X	FMEA: 2.1; FTA: Humidifier error, E10
Therapeutic	Humidifier	184	Faulty humidifier	Humidifier does not provide the correct level of humidification or dispenses an incorrect oxygen concentration	Mechanical fault	~	X	✓	X	This is a surprising omission in the FMEA. FTA: Humidifier Error, J.
Therapeutic	Humidifier	125	Undetected humidifier water depletion	Undetected humidifier water depletion	Lack of vigilance	X	✓	✓	X	FMEA: 2.2.4; FTA: Humidifier Error, E9, K

Subsystem	Component	Hazard ID	Hazard Type	Hazardous Element	Initiating Mechanisms	Delphi	FMEA	FTA	HAZOP	Notes
Therapeutic	Patient Connection	31	Spectacles or other obstructions on the face	Poorly fitting patient accessory	Spectacles or other obstructions on the face	X	~	✓	X	FMEA: 2.6.6; FTA: Equipment Failure. If Patient Connection Error tree had been done, this might have been present in that too.
Therapeutic	Patient Connection	177	Endotracheal tube blocked	Blocked endotracheal tube	Setup error, debris	~	~	~	X	FMEA: 2.6.14 (Very similar issues to Tracheostomies.); FTA: Generic in Equipment Failure.
Therapeutic	Patient Connection	160	Tracheostomy Complications	Loose or blocked tracheostomy	Setup error, patient movement, debris	~	✓	✓	X	FMEA: 2.6.14; FTA: Generic in Equipment Failure.
Therapeutic	Patient Connection	116	An accessory is incorrectly or inappropriately disconnected by clinical staff	Undetected accessory disconnection	Human error, Lack of Knowledge or Skill	~	X	✓	X	FTA: Equipment Failure
Therapeutic	Patient Connection	115	An accessory is displaced when a patient's position or posture is changed	Accessory displacement	Changing a patients posture or position	X	✓	✓	X	FMEA: 2.6.7; FTA: Applied Part Displacement, E4.
Therapeutic	Patient Connection	101	Failure to correct a displaced accessory	Misplaced accessory	Failure to act	X	~	✓	X	FMEA: 2.6.7; FTA: Applied Part Displacement, A.
Therapeutic	Patient Connection	90	The accessory has to be changed to relieve patient discomfort	Unsuitable accessory	Accessory causes discomfort	X	✓	~	X	FMEA: 2.6.1, 2.6.8c; FTA: Applied Part Displacement, E11,K
Therapeutic	Patient Connection	67	Accessory moved into an incorrect position by Patient	Misplaced accessory	Patients actions	X	✓	✓	X	FMEA: 2.6.7a, 3.1.4; FTA: Applied Part Displacement, E3
Therapeutic	Patient Connection	37	Physical failure of a patient connected accessory	Undetected accessory failure	Any physical or functional failure of any accessory	✓	✓	✓	X	FMEA: 2.6.9/10/11/12/13/14; FTA: Equipment Failure
Therapeutic	Tubing	118	Bubble tubing incorrectly cut	Undetected setup error	Human error	~	~	~	X	FMEA: 2.3.1; Tubing Error mentioned but unexplored.
Therapeutic	Tubing	213	Tubing damaged - Melted due to contact with hot surface	Contact between tubing and hot surfaces	Tubing routing error, Patient movements or actions	X	✓	~	X	FMEA: 2.3.5; FTA: Tubing Error mentioned but not yet explored.
Therapeutic	Tubing	110	Therapy tubing disconnected in error	Undetected tubing disconnection	Inappropriate or inadvertent action	✓	✓	~	X	FMEA: 2.3.6; FTA: Tubing Error mentioned but not yet explored.
Therapeutic	Tubing	189	Infection risk - Fungus in oxygen tubing	Fungal growth in oxygen tubing	Non-sterile water in humidifier, tubing in use for too long	X	X	X	X	
Therapeutic	Tubing	34	Tubing pinched in furniture or other equipment at the bed side	Damaged or occluded tubing	Poor tubing position	✓	✓	~	X	FMEA: 2.3.9; FTA: Tubing Error mentioned but not yet explored.